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A CLINICAL STUDY TO EVALUATE THE EFFECT OF YAVAKSHARADI VATI IN KANTHSHALOOK W.S.R. TO ADENOID HYPERTROPHY

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ABSTRACT

Background: Kanthshalook is described in Ayurvedic literature as a disease of the Kantha characterized by swelling, a thorn-like sensation and obstruction of the passage. In the present research paper Kanthshalook has been clinically correlated with adenoid hypertrophy. Adenoid hypertrophy is an obstructive condition involving enlargement of lymphoepithelial tissue in the nasopharynx and may be associated with mouth breathing, snoring, sleep disturbance, recurrent pharyngitis and otological symptoms.**Aim:** To evaluate the effect of Yavaksharadi Vati in the management of Kanthshalook w.s.r. to adenoid hypertrophy and to observe any untoward effects. **Materials and Methods:** The clinical study was conducted in the Shalakya Tantra OPD, Ten patients were included in the reported treatment-effect analysis. Patients received Yavaksharadi Vati for 15 days. Children received 4 mg/kg body weight twice daily with Sukhoshan Jala, while adults received 250 mg twice daily with Sukhoshan Jala. Follow-up was advised on the 7th day and at the end of the trial. Subjective criteria included mouth breathing, snoring,

otological symptoms, craniofacial abnormalities, sleep disturbance and recurrent pharyngitis. Objective assessment was performed by X-ray soft tissue lateral view of the skull using the Cohen and Konak grading method. **Results:** The reported percentage relief was 66.67% in mouth breathing, 42.31% in snoring, 37.50% in otological symptoms, 66.80% in sleep disturbance and 42.92% in recurrent pharyngitis. X-ray soft-tissue nasopharynx findings showed 36.36% improvement. No improvement was reported for craniofacial abnormalities. The reported within-group t-values included t=7.27 for mouth breathing, t=9 for snoring, t=5.55 for sleep disturbance and t=8.76 for recurrent pharyngitis, with corresponding reported p<0.001. Overall, 8 (80%) patients showed mild improvement and 2 (20%) showed marked improvement.**Conclusion:** Yavaksharadi Vati was associated with improvement in the assessed clinical symptoms and radiological findings in the reported treatment-effect analysis. No minor or major untoward effect was reported during the clinical study and follow-up.

KEYWORDS: Kanthshalook, Adenoid Hypertrophy, Yavaksharadi Vati.

INTRODUCTION

Shalakya Tantra is the branch of Ayurveda concerned with disorders of the organs and structures situated above the clavicle, including the nose, throat, ear, eye and oral cavity. Kanthshalook is described in Ayurvedic literature under Kanthagata Roga by Acharya Sushruta[1] and Acharya Vagbhata.[2]

The classical description includes swelling in the throat, a hard and stable mass-like structure, a thorn-like or bristle-like sensation and obstruction of the passage.[3,4] The article identifies these features as clinically resembling important manifestations of adenoid hypertrophy.

Adenoid hypertrophy is an obstructive condition associated with enlargement of adenoidal lymphoid tissue in the superior nasopharynx.[5] The adenoids form part of Waldeyer's ring and their size generally increases during childhood, reaching a maximum during early childhood before regression during adolescence.[6] Infectious and non-infectious factors have been discussed in the dissertation in relation to adenoid hypertrophy, including viral and bacterial infection, allergy, gastroesophageal reflux and exposure to cigarette smoke.[7]

Clinically, adenoid hypertrophy may interfere with nasal airflow and may be associated with mouth breathing, snoring, sleep disturbance, recurrent pharyngitis and otological

manifestations. Persistent obstruction may also be associated with craniofacial changes. Radiological assessment using a lateral soft-tissue nasopharyngeal X-ray was used in the present study to grade adenoid obstruction.[8]

Ayurvedic management of Kanthshalook is described within the framework of Kapha predominance and the use of therapies having Lekhana, Shothahara, Shodhana and related actions. Yavaksharadi Vati was selected as the oral intervention and was evaluated using clinical and radiological assessment.

CLINICAL RELEVANCE OF THE STUDY

The clinical availability of patients with adenoid-related complaints and the practical importance of evaluating conservative Ayurvedic management. The present paper therefore focuses specifically on the Yavaksharadi Vati and evaluates symptom-based and radiological outcomes in the ten patients included in the reported treatment-effect analysis.

AYURVEDIC CORRELATION WITH KANTHSHALOOK

From the Ayurvedic perspective adopted in this study, Kanthshalook is considered predominantly Kapha-related. Therefore, drugs possessing Kapha-shamaka, Lekhana, Shothahara and related actions were considered relevant to the obstructive manifestations of the condition. Yavaksharadi Vati was selected as the oral intervention for the treatment-effect analysis.

Kanthshalook has been correlated in the present research work with adenoid hypertrophy on the basis of similarities in the clinical presentation of obstruction and swelling in the throat region. Acharya Charaka has mentioned it in the Trishothiya Adhyaya as a Shaluka Roga, while Acharya Sushruta and Acharya Vagbhata have described it under Kanthagata Roga. Acharya Vagbhata has described its management along the lines of Kaphaja Rohini.

CLINICAL AND CONCEPTUAL BACKGROUND

Clinically, enlargement of adenoidal tissue may compromise the nasopharyngeal airway and may manifest as nasal obstruction, mouth breathing, snoring, recurrent rhinorrhoea, sleep disturbance, recurrent pharyngitis and otological manifestations related to Eustachian tube dysfunction. Persistent obstruction may be associated with adenoid facies and other craniofacial changes. These manifestations formed the clinical basis for assessment in the present study.

Adenoid hypertrophy may occur with or without acute or chronic infection. Infectious associations described in the synopsis include viral pathogens such as adenovirus, coronavirus, coxsackievirus, cytomegalovirus, Epstein–Barr virus, herpes simplex virus, parainfluenza virus and rhinovirus. Aerobic and anaerobic bacterial organisms have also been implicated. Non-infectious associations described include allergy, gastroesophageal reflux and exposure to cigarette smoke. In adults, adenoid enlargement may occasionally require evaluation for other underlying conditions.

Adenoid hypertrophy is an obstructive condition related to enlargement of the adenoidal lymphoid tissue in the superior nasopharynx. The adenoids are part of Waldeyer's ring and are situated in the nasopharynx medial to the Eustachian tube orifices. Adenoidal tissue normally enlarges during childhood and commonly reaches a maximum size during early childhood before physiological regression during adolescence.

AIM AND OBJECTIVES

To evaluate the effect of Yavaksharadi Vati in the management of Kanthshalook w.s.r. to Adenoid Hypertrophy.

To assess the effect of Yavaksharadi Vati on the subjective clinical parameters of adenoid hypertrophy.

To assess the effect of Yavaksharadi Vati on X-ray soft-tissue nasopharynx findings.

To observe any untoward effects of Yavaksharadi Vati during the treatment and follow-up period.

DRUG PROFILE OF YAVAKSHARADI VATI

Yavaksharadi Vati is a classical formulation described for disorders of the throat. The formulation used in the present study consisted of Yavakshara, Tejbal, Patha, Daruharidra, Rasanjana and Pippali in equal proportion, with Madhu as required for binding and preparation of the pills. The classical reference cited in the source is Chakradatta, Kanthagata Roga Chikitsa 56/83.

S. No.	Ingredient	Botanical/Source	Family	Part/Form	Quantity
1	Yavakshara[9]	Hordeium vulgare Linn.	Poaceae	Panchanga Kshara	1 part
2	Tejbal[10]	Zanthoxylum armatum DC	Rutaceae	Stem powder	1 part
3	Patha[11]	Cissampelos pareira Linn.	Menispermaceae	Root powder	1 part
4	Daruharidra[12]	Berberis aristata Linn.	Berberidaceae	Root powder	1 part
5	Rasanjana[13]	Berberis aristata Linn.	Berberidaceae	Root extract	1 part
6	Pippali[14]	Piper longum Linn.	Piperaceae	Fruit powder	1 part

7	Madhu[15]	Honey	—	Binder/vehicle	Q.S.

METHOD OF PREPARATION OF YAVAKSHARA

The whole mature Yava plant is collected and dried. The dried plant is completely burnt to obtain ash. The ash is soaked in eight times its quantity of water and kept undisturbed for 24 hours. The clear supernatant liquid is then filtered and allowed to evaporate completely. The residue obtained after evaporation is Yavakshara. The drug review describes potassium carbonate as the major alkaline constituent of Yavakshara.

METHOD OF PREPARATION OF YAVAKSHARADI VATI

Yavakshara is prepared as described above. Tejbal, Patha, Daruharidra and Pippali are cleaned, dried and reduced to fine powder. Rasanjana is used in its extract form. The six principal ingredients are taken in equal proportion (1 part each) and mixed uniformly. Madhu is then added in sufficient quantity as the binding medium and the mass is triturated until a homogeneous pill mass is obtained. Small, uniform Gudika/Vati are prepared from the mass and dried appropriately.

PROPERTIES AND THERAPEUTIC RATIONALE

The formulation as predominantly Kapha-pacifying and attributes actions such as Lekhana, Shothahara, Shodhana, Deepana/Pachana and relief of throat-related symptoms to its ingredients. These properties were considered relevant to the Kapha-dominant obstructive features of Kanthshalook correlated with adenoid hypertrophy.

OVERALL ASSESSMENT OF THERAPY

The study defined complete remission as 100% relief, marked improvement as 76–99% relief, moderate improvement as 51–75% relief, mild improvement as 25–50% relief, and unimproved as less than 25% relief in signs and symptoms.

OBJECTIVE RADIOLOGICAL ASSESSMENT

X-ray soft-tissue lateral view of the skull in extended neck was used for objective assessment of nasopharyngeal obstruction. The synopsis specified the Cohen and Konak grading method: Grade 1, 0–25% obstruction; Grade 2, 26–50%; Grade 3, 51–75%; and Grade 4, 76–100% obstruction due to adenoid tissue.[16]

DETAILED SUBJECTIVE ASSESSMENT

There are four-point scoring systems for the principal clinical parameters. Mouth breathing

and snoring were scored from 1 for absence to 4 for constant presence. Otological symptoms were scored from 1 for absence to 4 for severe chronic tubotympanic disease/impending cholesteatoma. Craniofacial abnormalities were scored from 1 for absence to 4 for the complete features of adenoid facies. Sleep disturbance was scored from 1 for absence to 4 for daily disturbance with more than three episodes per night. Recurrent pharyngitis was scored from 1 for absence to 4 for more than six episodes per year.

DOSE, DURATION AND FOLLOW-UP

The study specifies Yavaksharadi Vati at 4 mg/kg body weight twice daily with Sukhoshan Jala for children and 250 mg twice daily with Sukhoshan Jala for adults. It planned follow-up on the 7th day and at the end of the trial. The synopsis describes a 15-day treatment period.

JUSTIFICATION FOR SELECTION OF YAVAKSHARADI VATI

Kanthshalook is considered a Kapha-dominant disorder. The ingredients of Yavaksharadi Vati were selected on the basis of their described Kapha-shamaka properties and actions such as Lekhana and Shothahara, along with other reported therapeutic actions relevant to obstructive and inflammatory manifestations. The formulation was also selected considering its classical indication and availability.

STUDY PROTOCOL

The study described as a randomized, open clinical trial. Written informed consent of the patient or parent/guardian was to be obtained before inclusion. Ethical clearance from the Institutional Ethics Committee was planned before commencement of the clinical trial, and CTRI registration was planned before patient enrolment. Screening, patient information, informed consent and a structured case-record proforma formed part of the proposed protocol.

DIAGNOSTIC CRITERIA

Objective assessment was performed by X-ray soft-tissue lateral view of the skull in extended neck to assess the degree of nasopharyngeal airway obstruction due to adenoid tissue.

Diagnosis was based on the clinical signs and symptoms described in classical Ayurvedic literature and modern descriptions of adenoid hypertrophy. The clinical features listed in the synopsis included nasal obstruction, snoring, mouth breathing, frequent rhinorrhoea, epistaxis, feeding problems in children, conductive deafness due to Eustachian tube block,

cervical lymphadenopathy, otitis media and adenoid facies. General manifestations included anorexia, lethargy, poor development, bed-wetting and pigeon chest.

SELECTION OF THE DISEASE

Kanthshalook w.s.r. to adenoid hypertrophy was selected because patients with the relevant obstructive symptoms were available in the clinical setting and because adenoid hypertrophy may produce persistent nasal and upper-airway symptoms. The synopsis also identified the clinical need for evaluation of non-surgical approaches in appropriately selected patients.

PLAN OF STUDY

The research work was planned under two broad components: (i) conceptual study and (ii) clinical study. The conceptual component comprised detailed review of relevant Ayurvedic and modern texts, research papers and available departmental/college literature, together with review of the selected trial drug. The clinical component comprised enrolment, examination and systematic assessment of eligible patients with Kanthshalook w.s.r. to adenoid hypertrophy.

MATERIALS AND METHODS

Study Design and Setting

Patients were selected from the ENT OPD/IPD and details of each case were recorded in a pre-prepared research proforma. The dissertation states that the study was initiated after ethical approval and was registered under CTRI No. CTRI/2025/03/082558. The Institutional Ethics Committee approval cited in the dissertation is Ayu/IEC/2024/1415 dated 29/10/2024.

Study Subjects and Sample

The original clinical study registered 11 patients. 10 registered patients and received Yavaksharadi Vati. For the present paper, only the ten patients included in the reported treatment-effect analysis are considered.

Parameter	Yavaksharadi Vati
Intervention	Yavaksharadi Vati
Patients included in treatment-effect analysis	10
Treatment duration	15 days
Follow-up	7th day and end of trial

Inclusion Criteria

- Patients/guardians willing to participate in the trial.

- Patients selected on the basis of signs and symptoms of Kanthshalook w.s.r. to adenoid hypertrophy.
- Patients above 5 years of age.

Exclusion Criteria

- Patients suffering from malignancy, diabetes mellitus or hypertension.
- Immunocompromised patients.
- Patients with congenital deformity.
- Patients/guardians not willing to participate.

Criteria for Withdrawal

- Non-compliance with the treatment regimen.
- Patient or guardian request for withdrawal.
- Development of another co-morbidity requiring immediate pharmacological intervention.
- Adverse reaction to the trial drug.

Intervention

Yavaksharadi Vati was administered to children at 4 mg/kg body weight twice daily with Sukhoshan Jala, while adults received 250 mg twice daily with Sukhoshan Jala. The treatment duration was 15 days.

Assessment Criteria

Subjective criteria included mouth breathing, snoring, otological symptoms, craniofacial abnormalities, sleep disturbance and recurrent pharyngitis. Objective assessment was performed by X-ray soft tissue lateral view of the skull in extended neck. Adenoid obstruction was graded according to the Cohen and Konak method.

Grade	Adenoid obstruction
Grade 1	0–25%
Grade 2	26–50%
Grade 3	51–75%
Grade 4	76–100%

Statistical Analysis

The dissertation reports analysis in terms of mean, standard deviation and standard error. Paired Student’s t-test was used for within-group assessment.

RESULTS

Effect of Yavaksharadi Vati on Clinical and Radiological Parameters

Assessment criterion	Percentage relief/improvement in Group I
Mouth breathing	66.67%
Snoring	42.31%
Otological symptoms	37.50%
Craniofacial abnormalities	0%
Sleep disturbance	66.80%
Recurrent pharyngitis	42.92%
X-ray soft-tissue nasopharynx	36.36%

This intervention (Yavaksharadi Vati) showed 66.67% relief in mouth breathing, 42.31% in snoring, 37.5% in otological symptoms, 66.8% in sleep disturbance, 42.92% in recurrent pharyngitis and 36.36% improvement in X-ray soft-tissue nasopharynx findings. No improvement was reported for craniofacial abnormalities.

Within-Group Statistical Findings

Criterion	Reported t-value	Reported p-value	Interpretation in source
Mouth breathing	7.27	<0.001	Statistically significant
Snoring	9.00	<0.001	Statistically significant
Sleep disturbance	5.55	<0.001	Statistically significant
Recurrent pharyngitis	8.76	<0.001	Statistically significant

The source reports these examples of within-group t-tests for Group I. It reports the corresponding p-values as $p<0.001$.

Overall Effect of Therapy

Category	Number of patients	Percentage
Mild improvement	8	80%
Moderate improvement	0	0%
Marked improvement	2	20%
Unchanged	0	0%

Among the ten patients included in the reported treatment-effect analysis, 8 (80%) patients showed mild improvement and 2 (20%) patients showed marked improvement. No patient was reported as unchanged.

SAFETY

No minor or major complication or untoward effect was reported in the patients during the clinical study and follow-up, according to the dissertation.

DISCUSSION

Discussion on Selection of the Problem

The study selected Kanthshalook w.s.r. to adenoid hypertrophy because the classical description contains clinical features that resemble the obstructive manifestations of adenoid hypertrophy, including swelling, obstruction of the passage and difficulty in breathing. The study therefore attempted to examine an Ayurvedic therapeutic approach using clinical symptoms and radiological findings.

Discussion on Effect of Yavaksharadi Vati

In the treatment-effect analysis, Yavaksharadi Vati was associated with improvement in the assessed clinical parameters. The reported relief was highest among the listed subjective parameters for sleep disturbance (66.80%) and mouth breathing (66.67%), followed by recurrent pharyngitis (42.92%), snoring (42.31%) and otological symptoms (37.50%). The reported improvement in X-ray soft-tissue nasopharynx findings was 36.36%. Craniofacial abnormalities showed no improvement.

Probable Mode of Action

The study describes Kanthshalook as a Kapha-dominant disorder and selected Yavaksharadi Vati on the basis of the reported Kapha-pacifying and related actions of its ingredients. The drug review attributes Lekhana, Shothahara, Shodhana, Deepana/Pachana and related therapeutic actions to the formulation. These properties were considered relevant to the obstructive features of Kanthshalook correlated with adenoid hypertrophy.

CONCLUSION

Based on the reported teatment-effect analysis, Yavaksharadi Vati was associated with improvement in the assessed clinical symptoms and X-ray soft-tissue nasopharynx findings in patients of Kanthshalook w.s.r. to adenoid hypertrophy. The reported improvement included 66.67% in mouth breathing, 42.31% in snoring, 37.50% in otological symptoms, 66.80% in sleep disturbance, 42.92% in recurrent pharyngitis and 36.36% in X-ray findings. Overall, 80% of the ten patients showed mild improvement and 20% showed marked improvement. No untoward effect was reported during the study and follow-up.

The study states that larger samples and longer treatment/follow-up durations would be useful for further substantiation of the observed therapeutic response.

RESEARCH REQUIREMENTS

The study identified the requirement for a well-established library, laboratory facilities, current national and international journals, computer and internet facilities, statistical support, raw drugs and processing materials, and an appropriate pharmacy facility for preparation of the trial formulation.

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