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Original article

Exploratory studies on the therapeutic effects of *Kumarabharana Rasa* in the management of chronic tonsillitis among children at a tertiary care hospital of Karnataka

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ABSTRACT

The effect of an Ayurvedic poly-herbo-mineral formulation *Kumarabharana Rasa* (KR) in the management of chronic tonsillitis (*Tundikeri*) in children has been assessed in this study. This clinical study was a double-arm study with a pre- and post-test design at the outpatient level in a tertiary Ayurveda hospital attached to a teaching institute located in district headquarters in Southern India. Patients ($n = 40$) with chronic tonsillitis satisfying diagnostic criteria and aged between 5 and 10 years were selected from the outpatient Department of Kaumarbhritya, SDM College of Ayurveda and Hospital, Hassan. Among them, 20 patients were treated with *Kumarabharana rasa* (tablet form) at a dose of 500 mg once daily for 30 days (Group A). The other 20 patients were treated with *Godhuma Vati* (placebo) at a dose of 500 mg once daily for 30 days (Group B). In both groups, *Madhu* was the *Anupana* advised. After completion of 30 days of treatment, the patients were assessed on the following day and another investigation took place 15 days later. Statistically significant effects ($p < 0.05$) in the reduction of all signs and symptoms of chronic tonsillitis after KR treatment were observed. These results indicate that *Kumarabharana Rasa* has an ameliorative effect in reducing the signs and symptoms of chronic tonsillitis.

1. Introduction

Chronic tonsillitis (CHT) is one of the most common otolaryngologic diseases.[1] CHT is rare in infants and older people. In young children, tonsillitis is one of the recurrent upper respiratory tract infections. CHT is a highly prevalent disease in the pediatric age group, and it peaks between 3 and 10 years of age and then declines.[2,3] In general practice children frequently visit with recurrent throat problems[4] and the incidence of this disease accounts for about 7% of all visits to the pediatrician.[3] Children with CHT experience discomfort, and the disease also impacts on social, emotional, and financial aspects for family members.[5] Tonsilitis is an infection of the tonsils.[6–8] Despite its high prevalence, the etiology of CHT has remained indistinct. The surface and deep bacterial flora of chronic inflamed tonsils consist of an abundance of probable pathogenic aerobic and anaerobic bacteria, primarily of streptococcal origin.[9–13] Tonsils are part of the immune system. Therefore, due to the decrease in immunity and the tonsils' incompetence in helping the immune system, they actually become a source of recurrent infections.[3] The current treatment option for CHT is tonsillectomy, but it is not the ultimate solution. The generally accepted criteria for tonsillectomy are at least three to seven episodes of tonsillitis per year in spite of medical therapy, but there is no international consensus.[14]

In Ayurvedic thought, tonsillitis can be correlated to *Tundikeri*, which is one of the *Urdhvajatrugata Roga* (diseases of the head and neck); it is mentioned in *Talugata Roga*[15] (diseases of the palate) as well as *Kanthagata Roga* (diseases of the throat).[16] Ayurveda explains that it is caused by the vitiation and imbalance of *Doshas*

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(bodily humors), i.e., *Vata, Pitta*, and *Kapha*. Mainly derangement of *Kapha* and *Rakta* (blood) is preceded by impaired digestive capacity (*Mandagni*/*Vishamagni*) and obstruction of channels (*Sroto Avarodha*) namely *Annavaha Srotas* (gastrointestinal tract) and *Pranavaha Srotas* (respiratory tract) which is manifested as difficulty in swallowing, mouth breathing, choking spells at night, etc.[15,16] The present study was conducted to explore the efficacy of *Kumarabharana Rasa* (KR) in the management of chronic tonsillitis in children. KR has a combined action over vitiated *Doshas* due to its anti-inflammatory, antimicrobial, immunomodulatory, and rejuvinative effects.

2. Materials and methods

2.1. Design

This study was an open-labeled double-arm setting with a pre- and post-test design.

2.2. Participants

Children presenting with any of the symptoms of chronic tonsillitis (*Tundikeri*), i.e., *Kathina Shotha* (enlargement of tonsils), *Ragatwa* (hyperemia), *Galoparodha* (dysphagia), *Mukha Daurgandhya* (halitosis), *Lasikagranthi Vriddhi* (enlargement of lymph nodes), and *Jwara* (fever) were selected and registered from *Kaumarabhritya* (Ayurvedic Pediatrics) outpatient department of SDM College of Ayurveda and Hospital, Hassan between June 2012 and December 2013. Before initiating the study ethical clearance was obtained from institutional ethics committee of SDM College of Ayurveda and Hospital, Hassan (IEC No. SDMAH/IEC/57/11-12 dated 01-04-2012). Written informed consent was taken from the parents of the study participants before any study-related procedures were performed. Inclusion criteria were: children of both sexes between 5 and 10 years of age and who had repeated attacks of tonsillitis (chronic infections) in the past year. Exclusion criteria were: patients with acute tonsillitis, peritonsillar abscess, tonsillar cyst, tonsillolith, or any other systemic disorders; patients who had taken systemic steroids and/or antibiotics in the past 4 weeks.

2.3. Study drugs

2.3.1. Kumarabharana Rasa

This is a compound drug comprising *Bhasmas* (purified calx) of Swarna (gold), Rajata (silver), Pravala (coral) and *Churna* (powder) of Yastimadhu (*Glycyrrhiza glabra* Linn.), Amlaki (*Emblica officinalis* Gaertn.), Ashwagandha (*Withania somnifera* Dunal.), Sunthi (*Zingiber officinale* Rosc.), Pippali (*Piper longum* Linn.), Haritaki (*Terminalia chebula* Retz.), Vacha (*Acorus calamus* Linn.). All these drugs were processed with *Swarasa* (extract juice) of Guduchi (*Tinospora cordifolia* Miers ex Hook. F. & Thoms), Brahmi (*Centella asiatica* Linn.), and Tulsi (*Ocimum tenuiflorum* Linn.) separately then prepared in tablet form.[17]

2.3.2. Godhuma Vati (placebo)

Wheat powder was processed and prepared in tablet form.

Raw drugs were obtained from SDM Pharmacy, Udupi and authenticated in the Department of Dravyaguna, SDM College of Ayurveda and Hospital, Hassan. The medicine was prepared in the Teaching Pharmacy, SDM College of Ayurveda and Hospital, Hassan. Tablets of 500 mg were prepared and preserved in air-tight, properly labeled plastic bottles containing 30 tablets in each.

2.4. Intervention

A total of 53 patients were screened for chronic tonsillitis. Among them 40 patients were enrolled into the study fulfilling the inclusion and exclusion criteria. A convenient sampling technique was adopted, with 20 patients each in study group (KR) and the control group (*Godhuma Vati*). The patients in the study group were treated with KR (tablet form) at a dose of 500 mg once daily for 30 days. The patients in the control group were treated with *Godhuma Vati* (tablet form) at a dose of 500 mg once daily for 30 days. Parents were advised to crush the tablet to a powder and to give it to the child using honey as *Anupana* (vehicle for drug administration) before food, in the morning, for both groups.

2.5. Observation-based assessment criteria

2.5.1. Subjective parameters

The assessment of the signs and symptoms were done on the Day 0 and Day 31. Severity was assessed by grading 1–5 (absence to severe) for each symptom. *Kathina Shotha* (enlargement of tonsils) – no enlargement, enlarged within anterior pillars, enlarged within posterior pillars, enlarged beyond pillars, kissing tonsils with sleep apnea. *Ragatwa* (hyperemia) – no hyperemia, hyperemia of tonsil surface, pinkish appearance of pillars, reddish appearance of surroundings, reddish appearance of surroundings and pharynx. *Galoparodha* (dysphagia) – no pain while swallowing, pain during swallowing solid food substances, pain during swallowing semi-solid food substances, pain during swallowing liquid food substances, continuous pain/unable to swallow. *Mukha Daurgandhya* (halitosis) – no halitosis, foul breath experienced by the patient only, foul breath experienced by the patient and friends/parents, foul breath is experienced by a group of surrounding people, foul breath is experienced as soon as the patient opens the mouth. *Lasikagranthi Vriddhi* (enlargement of lymph nodes) – no palpable lymph nodes, palpable lymph nodes unilateral/warm, palpable lymph nodes bilateral/soft/fluctuant, palpable lymph nodes bilateral which are hard, palpable lymph nodes bilateral with tenderness. *Jwara* (fever) was measured according in degrees Fahrenheit (normal was 98.6° Fahrenheit).

2.5.2. Objective parameters

Assessments were based on routine laboratory blood investigations – hemoglobin % (Hb%), total leukocyte count (TLC), neutrophils, lymphocytes, eosinophils, and erythrocyte sedimentation rate (ESR) were performed on Day 0 and Day 31.

2.6. Statistical analysis

For the statistical analysis, the Statistical Package for Social Sciences (SPSS) version 16 (SSPS Inc., Chicago. IL, USA) was used. The independent samples *t* test and Mann-Whitney *U* test (for between-subjects designs) and paired samples *t* test and the Wilcoxon test (for within-subjects designs) were done.

3. Results

In present study 40 patients were registered, of which only 37 participants completed the study. The sociodemographic profile of the participants shows that 57.5% (23) were male and the rest 42.5% (17) were females. The age groups of 5–6, 7–8, and 9–10 years consisted of 18 (45%), 27.5% (11), 27.5% (11) participants, respectively. The majority (90%, 36) of the participants belonged to the Hindu religion. Socioeconomic assessment revealed that 37.5% belonged to the lower-middle class followed by 30% in the upper-middle class strata. *Prakriti* (genetic phenotype) yielded the