EFFECT OF KUMARABHARANA RASA ON CHRONIC TONSILLITIS IN CHILDREN:
A PILOT CLINICAL STUDY

Shailaja U¹*, Rao Prasanna N², Arun Raj GR¹, Mallannavar V⁴¹

¹Professor and Head, ²Principal and CMO, ³Postgraduate scholar, ⁴Lecturer, Department of PG Studies in Kaumarabhritya, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, BM Road, Thanniruwalla, Hassan, Karnataka, India

ABSTRACT
Objective of the study was to assess the effect of Kumarabharana Rasa in the management of chronic tonsillitis (Tundikeri) in children. This study was pilot clinical study with single arm with pre and post test design at outpatient level in a tertiary Ayurveda hospital attached to teaching institute located in district headquarters in Southern India. 16 patients of chronic tonsillitis satisfying diagnostic criteria and age 5-10 years were selected from outpatient department of Kaumarabhritya, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. Patients were treated with Kumarabharana rasa (tablet form) in the dose of 500mg once daily for 30 days. The percentage of relief in various assessment criteria were observed which are Kathina shotha (enlargement of tonsils) (43.20%), Ragatwa (hyperemia) (48.83%), Galoparodha (dysphagia) (47.48%), Mukha daargandhya (halitosis) (49.68%), Lasikragranti vridhi (enlargement of lymph nodes) (37.72%) and Jwara (improvement in fever) (85.71%). Kumarabharana Rasa is effective in reducing the signs and symptoms of chronic tonsillitis.

Keywords: Kumarabharana Rasa, chronic tonsillitis in children, Tundikeri

INTRODUCTION
Tundikeri (Tonsillitis) is a highly prevalent disease in paediatric age from 5-10 years.¹ Tonsillitis is an infection of tonsils, which are glands on either side of the back of the throat. The tonsils are part of the immune system, which protects and helps the body to fight infections. Tonsils aid the body in fighting off diseases and infection in children. The tonsil tissues can become diseased with recurrent infections. When this happens, they lose their effectiveness in helping the immune system and actually become a source of recurrent infection. Hence, timely treatment is most essential.² The recurrent attack of tonsillitis makes the disease chronic and vulnerable for infectious diseases. Several health hazards like laryngeal oedema, acute otitis media, quinsy, rheumatic fever, rheumatic heart diseases are often seen³. In Ayurvedic purview, tonsillitis can be correlated to Tundikeri. Tundikeri is one among the Urdhvaatragata roga; mentioned in Talugatara⁴ as well as Kanthagataroā.⁵ Kumarabharana Rasa is a compound drug comprising of Bhasmas (calx) of Swarna (Gold), Rajata (Silver), Pravala (coral) and Choorna of Yastimadhu (Glycyrrhiza glabra), Amalaki (Emblica officinalis), Ashwagandha (Withania somnifera), Shunti (Zingiber officinale), Pippali (Piper longum), Haritaki (Terminalia chebula), Vacha (Acorus calamus) and all these drugs given one Bhavana with Swaras (extract juice) of Guduchi (Tinospora cordifolia), Brahmi (Bacopa monnieri) and Tulsi (Ocimum tenuiflorum) separately.

MATERIALS AND METHODS
Objective: To assess the effect of Kumarabharana rasa in chronic tonsillitis in children.

Source of Data: Patients were selected successively from the outpatient department of Kaumarabhritya, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. Ethics clearance was obtained from Institutional Ethic committee of SDM College of Ayurveda and Hospital, Hassan (IEC No. SDMAH/IEC/57/11-12 dated 01-04-2012).

Method of collection of data
Diagnostic Criteria
Diagnosis were made on the basis of symptoms of Tundikeri i.e. Katina Shotha (enlargement of tonsils), Ragata (hyperemia), Galoparodha (dysphagia), Mukha daargandhya (halitosis), Lasikragranti vridhi (enlargement of lymph nodes) and Jwara (fever).⁶

Inclusion criteria
Children of both genders between 5-10 years of age, who were suffering from 3-4 attacks of chronic tonsillitis in a year.

Exclusion criteria
Patients with peritonsillar abscess, tonsillar cyst, tonsillolith or with any other systemic disorders were excluded.

Research design
Selected 16 patients of Tundikeri were taken for clinical trial. Patients were treated with Kumarabharana rasa (tablet form) in the dose of 500 mg tablet once daily for 30 days. Parents were advised to crush the tablet to powder and be given to the patient using honey as anupana before food in the morning.
Method of Preparation of Kumarabharana Rasa

Ingredients with Sanskrit and botanical name, form and proportion are detailed in Table 1. Raw drugs were obtained from SDM Pharmacy, Udupi and authenticated in Dept of Dravyaguna, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. The medicine was prepared in Teaching Pharmacy, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. Fine powder of Vacha, Pippali, Shunthi, Ashwagandha, Amalaki, Haritaki and Yastimadhu along with bhasmas of Swarna, Rajata and Pravala were taken and one bhavana (impregnation) with each of Guduchi swarasa, Brahmi swarasa and Tulsi swarasa was given. Tablets of 500 mg were prepared and preserved in air tight, properly labelled bottle with 10 tablets in each.

Laboratory Investigations: Investigations like Haemoglobin%, Total leukocyte count, Differential leukocyte count, and Erythrocyte sedimentation rate were done before and after treatment.

Assessment Criteria

Suitable scores were assigned to assess changes in clinical features of tonsillitis such as Kathina shotha (enlargement of tonsils), Ragata (hyperemia), Galoparodha (dysphagia), Mukha daurgandhya (halitosis), Lasikgranthi vridhdi (enlargement of lymph nodes) and Jwara (fever). The adopted scale was validated under Cronbach’s alpha (α=0.68).

1. Enlargement of tonsils (Kathina shotha)
1. – No Enlargement
2. – Enlarged within anterior pillars
3. – Enlarged within posterior pillars
4. – Enlarged beyond pillars
5. – Kissing tonsils with sleep apnoea

Grading of tonsillar size is detailed in figure 1.

2. Hyperemia (Ragatwa)
1. – No Hyperaemia
2. – Hyperaemia of tonsil surface
3. – Pinkish appearance of pillars
4. – Reddish appearance of surroundings
5. – Reddish appearance of surroundings and pharynx

3. Dysphagia (Galoparodha)
1. – No pain while swallowing
2. – Pain during swallowing solid food substances
3. – Pain during swallowing semi-solid food substances
4. – Pain during swallowing liquid food substances
5. – Continuous pain/unable to swallow

4. Halitosis (Mukha daurgandhya)
1. – No halitosis
2. – Foul breathe experienced by patient only
3. – Foul breathe is experienced by patient and friends/parents
4. – Foul breathe is experienced by a group of surrounding people
5. – Foul breathe is experienced as soon as the patient opens the mouth

5. Enlargement of lymph nodes (Lasika granthi vridhdi)
1. – No palpable lymph nodes
2. – Palpable lymph nodes unilateral/warm
3. – Palpable lymph nodes bilateral/soft/fluctuant
4. – Palpable lymph nodes bilateral which are hard
5. – Palpable lymph nodes bilateral with tenderness

6. Improvement in fever (Jwara)
1. – Normal Temperature – 98.6°F
2. – Temperature rises from 98.6°F – 100°F
3. – Temperature rises from 100°F – 101°F
4. – Temperature more than 101°F
5. – Temperature more than 101°F with fatigue

Table 1: Ingredients of Kumarabharana rasa

<table>
<thead>
<tr>
<th>Sanskrit Name</th>
<th>Botanical Name</th>
<th>Form</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swarna</td>
<td>Withania somnifera</td>
<td>Bhasma</td>
<td>1 part</td>
</tr>
<tr>
<td>Rajata</td>
<td>Emblica officinalis</td>
<td>Bhasma</td>
<td>2.5 parts</td>
</tr>
<tr>
<td>Pravala</td>
<td>Bhasma</td>
<td>5 parts</td>
<td></td>
</tr>
<tr>
<td>Ashwagandha</td>
<td>Churna</td>
<td>40 parts</td>
<td></td>
</tr>
<tr>
<td>Amalaki</td>
<td>Emblica officinalis</td>
<td>Churna</td>
<td>50 parts</td>
</tr>
<tr>
<td>Shunthi</td>
<td>Zingiber officinalis</td>
<td>Churna</td>
<td>20 parts</td>
</tr>
<tr>
<td>Pippali</td>
<td>Piper longum</td>
<td>Churna</td>
<td>10 parts</td>
</tr>
<tr>
<td>Haritaki</td>
<td>Terminalia chebula</td>
<td>Churna</td>
<td>10 parts</td>
</tr>
<tr>
<td>Vacha</td>
<td>Acorus calamus</td>
<td>Churna</td>
<td>10 parts</td>
</tr>
<tr>
<td>Yastimadhu</td>
<td>Glycyrrhiza glabra</td>
<td>Churna</td>
<td>50 parts</td>
</tr>
</tbody>
</table>

Table 2: Effect of therapy on clinical features of chronic tonsillitis

<table>
<thead>
<tr>
<th>Parameters</th>
<th>N</th>
<th>BT</th>
<th>AT</th>
<th>SD</th>
<th>SEM</th>
<th>T</th>
<th>P</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shotha</td>
<td>16</td>
<td>3.31</td>
<td>1.88</td>
<td>0.51</td>
<td>0.13</td>
<td>11.22</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Ragatwa</td>
<td>16</td>
<td>2.56</td>
<td>1.31</td>
<td>0.45</td>
<td>0.11</td>
<td>11.18</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Galoparodha</td>
<td>16</td>
<td>2.38</td>
<td>1.25</td>
<td>0.50</td>
<td>0.13</td>
<td>9</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Halitosis</td>
<td>14</td>
<td>1.57</td>
<td>0.79</td>
<td>0.70</td>
<td>0.19</td>
<td>4.2</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Enlargement of lymph Nodes</td>
<td>16</td>
<td>2.81</td>
<td>1.75</td>
<td>0.25</td>
<td>0.06</td>
<td>17</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>Improvement In Fever</td>
<td>16</td>
<td>1.75</td>
<td>0.25</td>
<td>0.63</td>
<td>0.16</td>
<td>9.49</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
</tbody>
</table>

HS – Highly significant
RESULTS

The data were collected and classified as follows for easy assessment.

- Demographic data and clinical status of children with chronic tonsillitis
- Data related to response of treatment

Demographic data

Age wise distribution of registered subjects shows that 62% were from 5-8 yrs age group and 38% of children were from 8-10 yrs age group. Sex wise distribution showed that 56% were males and 44% were females. The religion based distribution showed that 75% of the children were Hindus, 19% were Muslims and 6% were Jain. The socio-economic status based distribution showed that 50% belonged to poor socioeconomic status, 36% belonged to middle class, and 14% were from upper class. Domicile based distribution showed that 69% were belonged to urban and 31% were belonged to rural area. Diet based distribution showed that 56% were vegetarian and 44% were mixed. Maximum children (50%) were of Vatakapha prakriti, followed by Pittakapha prakriti (44%) and Vatapitta prakriti (6%). Majority of the subjects (69%) had Mandagni (poor digestive capacity), rest 31% had Vishamagni (inconsistent digestive capacity). Distribution according to nutritional status showed that 19% had poor nutritional status, 56% had adequate nutrition, and 25% had moderate nutritional status. In 81% subjects, duration of the onset of the disease was since 3 and above 3 years; in 13% cases, onset was since 2 years and in 6% cases onset was since 1 year. Distribution according to the type of chronic tonsillitis showed that 56% had chronic fibroid tonsillitis, 31% had chronic parenchymatous tonsillitis and 13% had chronic follicular tonsillitis.

Data related to response to treatment

In the study, it was attempted to measure the effectiveness of the treatment by assessing signs and symptoms by adopting scoring technique. Effect of therapy on clinical features of chronic tonsillitis are detailed in Table 2. Percentage wise relief in sign and symptoms after treatment is detailed in Graph 1.

DISCUSSION

All the 16 patients satisfying the inclusion criteria were given the medicine for a period of 30 days and were assessed before and after treatment. The subjective and objective parameters were graded for statistical evaluation. The data were encoded in the case sheet and assessment chart and the observations were analyzed using appropriate statistical methods (Student t test).

All the assessment criteria’s such as Katina shotha (enlargement of tonsils), Ragata (hyperemia), Galoparodha (dysphagia), Mukha daurgandhya (halitosis), enlargement of lymph nodes and Jwara (fever) were assessed before and after treatment. The effect of therapy in Katina shotha (enlargement of tonsils) is 43.20%, in Ragata (hyperemia) is 48.83%, in Galoparodha (dysphagia) is 47.48%, in Mukha daurgandhya (halitosis) is 49.68%, in enlargement of lymph nodes is 37.72% and in Jwara (fever) it is 85.71%. Thus trial drug has reduced signs and symptoms of chronic tonsillitis which is statistically significant (p < 0.001).

Probable mode of action of Kumarabharana Rasa

Tundikeri is caused due to the vitiation of Kapha and Rakta and is preceded by impaired digestive capacity (mandagni / vishamagni) and obstruction of channels (sroto avaroda) which is manifested as difficulty in swallowing, mouth breathing, choking spells at night etc. The formulation Kumarabharana Rasa contains 10 ingredients. Among them bhasmas of Swarna (Gold), Rajata (Silver), Pravala (Coral) and Choornas of Yasimadhul (Glycyrrhiza glabra), Amalaki (Emblica officinalis), Ashwagandha (Withania somnifera), Shunti (Zingiber officinale), Pippali (Piper longum), Haritaki (Terminalia chebula), Vacha (Acorus calamus), is having Anulomana (carminative) property. Swarna bhasma is prepared by incinerating gold processed with herbal preparations. Swarna bhasma promotes immunity through phagocytosis. Gold is one of the noble metals used in continuity to increase the vitality and immunity. The clinical applications of Swarna bhasma and gold salts are integrated both in Ayurveda and Medical science for rejuvenation and immunomodulation for some chronic diseases. In Ayurveda, herbo-mineral compounds are used for healing properties with an objective to health promotion.

Amalaki and Guduchi are having Balya (nourishing) and Rasayana (rejuvenative) property. Guduchi is widely used for the treatment of diabetes, arthritis and inflammation. Experimental studies reveal that it is immunostimulant and combats sepsis in animals.
Thus the trial drug is having a combined action over vitiated doshas (channels) i.e. Annavaha Srotas (gastrointestinal tract) and pranavaha srotas (Respiratory tract) by virtue of its Kaphahara, Shophahara (anti-inflammatory), Lekhana (scraping), Deepana (dissociative), Pachana (dissociative), Anulomana (carminative), Balya (nourishing) and Rasayana (rejuvenating) effect due to the domination of bitter taste (tikta rasa), Katu rasa (pungent taste), Kashaya rasa (astringent), Ushna veerya (the pharmacokinetic principles), Laghu guna (lightness), Ruksa guna (dryness) and thus effective in reducing the signs and symptoms of chronic tonsillitis.

CONCLUSION

Statistically significant effect (p <0.001) of Kumarabharana Rasa in reduction of all signs and symptoms of chronic tonsillitis after treatment was observed. It may be concluded from the pilot clinical study that Kumarabharana Rasa is effective in reducing the signs and symptoms of chronic tonsillitis (Tundikeri) hence the said drug is useful in the management of chronic tonsillitis in children.

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