

CLINICAL EVALUATION OF KANTAKARI AVALEHA IN THE MANAGEMENT OF KASA (COUGH) IN CHILDREN: AN OPEN-LABEL SINGLE-ARM CLINICAL STUDY

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ABSTRACT

Background. Cough is one of the common respiratory complaints encountered in children. Ayurveda describes Kasa as a distinct disease involving the Pranavaha Srotas, with Vata and Kapha playing important roles in its pathogenesis. Kantakari Avaleha is a classical Ayurvedic formulation traditionally used in respiratory disorders. **Aim.** To clinically evaluate the effect of Kantakari Avaleha in the management of Kasa in children aged 5–12 years. **Materials and Methods.** A prospective, open-label, interventional, single-arm clinical study was conducted in 60 children aged 5–12 years. Kantakari Avaleha was administered according to the study protocol. Clinical assessment was performed at baseline and during follow-up, with subjective and objective parameters and selected laboratory investigations. Statistical analysis used paired t-test. **Results.** Thirty-three participants (55%) were

male and 27 (45%) female; 36 (60%) were aged 8–10 years. Cough bouts per hour decreased from a mean score of 2.96 before treatment to 1.16 after treatment, corresponding to 60.81% improvement ($p < 0.0001$). Sleep disturbance improved by 59.70%, throat infection by 61.57%, wheeze by 49.41%, crepitations by 76.08% and sputum by 59.71%. Overall, 15 children (25%) had $\geq 75\%$ relief, 30 (50%) had 51–75% relief, 13 (21.67%) had 25–50% relief and 2 (3.33%) had 1–25% relief. No adverse effects were reported during the study period. **Conclusion.** Kantakari Avaleha was associated with improvement in clinical features of Kasa and was well tolerated during the 21-day observation period. Because this was an

open-label single-arm study, controlled comparative studies with larger samples and longer follow-up are required.

KEYWORDS: Kasa; cough; Kantakari Avaleha; Ayurveda; children; Kaumarbhritya; Pranavaha Srotas.

INTRODUCTION

Cough is among the common respiratory symptoms encountered in childhood and may accompany upper respiratory tract infections and other respiratory conditions. Its clinical significance depends on duration, associated symptoms and the underlying condition. Appropriate assessment is therefore important in children presenting with recurrent or persistent cough.^[1,2]

Ayurveda describes Kasa as both a symptom and an independent disease entity. Classical texts describe different varieties of Kasa and discuss the role of Vata and Kapha in its pathogenesis. Kapha-associated manifestations include increased respiratory secretions, anorexia, nausea, coryza and impaired digestive function.^[3]

Childhood is considered a Kapha-dominant stage of life in Ayurvedic thought. Dietary and environmental factors such as excessive intake of Guru, Sheeta, Abhishyandi and Madhura foods, exposure to dust and smoke, and cold environments are described as relevant aggravating factors. These factors were also frequently recorded in the present clinical population.

Kantakari is traditionally used in respiratory disorders. Kantakari Avaleha contains Kantakari along with Guduchi, Chavya, Chitraka, Musta, Karkatashringi, Maricha, Pippali, Shunthi, Dhanvayasa, Bharangi, Rasna, Shati, Vanshalochana, Sita, Madhu, Ghrita and Tila Taila. The formulation is traditionally interpreted as having Kasahara, Kapha-Vata balancing, Deepana and Pachana properties.^[4,5]

Despite traditional clinical use, clinical evidence specifically evaluating Kantakari Avaleha in children with Kasa remains limited. The present study was therefore undertaken to evaluate its clinical effect in children aged 5–12 years.

AIM AND OBJECTIVES

Aim: To evaluate the clinical effect of Kantakari Avaleha in the management of Kasa in children aged 5–12 years.

- To assess the effect of Kantakari Avaleha on subjective symptoms of Kasa.
- To assess its effect on objective clinical parameters associated with cough.
- To assess changes in selected laboratory parameters.
- To document tolerability and adverse effects, if any, during the study period.

MATERIALS AND METHODS

Study design and setting

The study was a prospective, open-label, interventional, single-arm clinical study conducted in the Department of Kaumarbhritya, Shri Dhanwantri Ayurvedic Medical College & Research Centre, Mathura, Uttar Pradesh. Sixty children fulfilling predefined eligibility criteria were enrolled.

Ethical approval and consent

The dissertation records Institutional Ethics Committee approval (IEC No. 2023/36/2026) and states that clinical trial registration was obtained before enrolment. Written informed consent was obtained from the parents or legal guardians of participating children. CTRI Registration No. : - CTRI/2026/04/107660

Participants

Children aged 5–12 years presenting with clinical features of Kasa and having cough on and off during the preceding six months were considered for enrolment.

INCLUSION CRITERIA

- Children aged 5–12 years.
- Presence of cardinal clinical features of Kasa.
- Cough occurring on and off for the preceding six months.
- Participants irrespective of sex, religion or socioeconomic status, provided other eligibility criteria were fulfilled.

EXCLUSION CRITERIA

- Age below 5 years or above 12 years.
- Cough of less than six months' duration.

- Congenital deformity relevant to the clinical condition.
- Cases requiring hospitalization.
- Cases requiring surgical intervention.
- Chronic infectious or major respiratory disorders specified in the protocol, including tuberculosis, bronchial asthma, AIDS or cystic fibrosis.

Intervention and dosage

Kantakari Avaleha was administered according to the clinical-trial protocol for a maximum treatment period of seven days, followed by a seven-day follow-up period, as described in the thesis abstract. The clinical-study section also describes a 21-day assessment schedule with visits on days 7, 14 and 21. The dose documented in the thesis abstract was 3 g twice daily for children aged 5–9 years and 6 g twice daily for children aged 10–12 years, after food with lukewarm water. Because another section of the thesis lists a different pharmacopoeial dose, the investigators should verify the actual administered dose from the original protocol/CRF before submission.

Composition

Table 1: Ingredients of Kantakari Avaleha.

S. No.	Ingredient	Ayurvedic name
1	Kantakari	Kantakari
2	Guduchi	Guduchi
3	Chavya	Chavya
4	Chitraka	Chitraka
5	Musta	Musta
6	Karkatashringi	Karkatashringi
7	Black pepper	Maricha
8	Long pepper	Pippali
9	Dry ginger	Shunthi
10	Dhanvayasa	Dhanvayasa
11	Bharangi	Bharangi
12	Rasna	Rasna
13	Shati	Shati
14	Bamboo silica	Vanshalochana
15	Sugar	Sita
16	Honey	Madhu
17	Ghee	Ghrita
18	Sesame oil	Tila Taila

PREPARATION

According to the thesis protocol, Kantakari Panchanga decoction was prepared and reduced to one-fourth of its original volume before filtration. The prescribed powdered ingredients

were incorporated with sugar, Ghrita and Tila Taila and processed with continuous stirring until Avaleha consistency was obtained. After cooling, Prakshepa Dravyas including Vanshalochana and Pippali were incorporated, followed by addition of Madhu after adequate cooling. The final product was stored in airtight containers.

Outcome assessment

Clinical assessment used a predefined 0–3 severity grading system. Subjective parameters included Nisthivateghanam Kapha, Jwara, Utklesha, Peenasa, Murdhashoola, Mandagni, Prasaktavega, Vamana, Ksheena Bala, Aruchi and Mukha-Kantha Shushkata. Objective parameters included cough bouts per hour, sleep disturbance, throat infection, wheezing, crepitations and sputum. Laboratory investigations included complete blood count, erythrocyte sedimentation rate and absolute eosinophil count; chest radiography was performed when required.

Statistical analysis

Data were analysed using GraphPad InStat. Mean, standard deviation, standard error, mean difference and percentage improvement were calculated. Pre- and post-treatment values were compared using paired t-test. A p-value <0.05 was considered statistically significant, <0.01 very significant and <0.001 highly significant.

RESULTS

Demographic characteristics

Table 2: Demographic characteristics of study participants.

Characteristic	n	%
Age 5–7 years	9	15
Age 8–10 years	36	60
Age 11–12 years	15	25
Male	33	55
Female	27	45
Total	60	100

The largest age group was 8–10 years (60%). Male participants constituted 55% and female participants 45% of the sample.

Clinical profile

Sudden onset was reported in 48 children (80%), while 42 (70%) had episodic attacks. Thirty-four (56.66%) had predominantly daytime symptoms and 29 (48.33%) reported food-

related aggravation. Kaphavataja Prakriti was documented in 39 children (65%). Guru, Sheeta, Abhishyandi and Madhura food exposure was reported in 48 children (80%), Sheeta Asana in 33 (55%) and Dhooma-Rajo Upaghata in 30 (50%).

The most frequent clinical feature was Nisthivateghanam Kapha in 48 children (80%), followed by Aruchi in 39 (65%), and Jwara and Utklesha in 36 (60%) each.

Subjective outcomes

Table 3: Percentage improvement in subjective parameters.

Parameter	Improvement (%)
Nisthivateghanam Kapha	65.61
Jwara	89.47
Utklesha	53.57
Peenasa	62.54
Murdhashoola	59.7
Mandagni	89.39
Prasaktavega	62.91
Vamana	58.75
Ksheena Bala	61.57
Aruchi	76.08
Mukha-Kantha Shushkata	93.53

Improvement ranged from 53.57% for Utklesha to 93.53% for Mukha-Kantha Shushkata.

OBJECTIVE OUTCOMES

Table 4: Objective clinical outcomes.

Parameter	Mean BT	Mean AT	Improvement (%)	p-value
Cough bouts/hour	2.96	1.16	60.81	<0.0001
Sleep disturbance	2.73	1.1	59.7	<0.0001
Throat infection	1.9	0.73	61.57	<0.0001
Wheeze	2.9	1.47	49.41	<0.001
Crepitations	2.76	0.66	76.08	<0.0001
Sputum	2.83	1.14	59.71	<0.0001

BT: before treatment; AT: after treatment.

Laboratory outcomes

Table 5: Selected laboratory parameters.

Parameter	Mean BT	Mean AT	Percentage change
TLC	9150	8370	8.52
Neutrophils	57.93	48.53	16.22
Eosinophils	5.73	4.57	20.41
ESR	17.47	15.73	9.95
Lymphocytes	36.33	42.1	Not specified

The thesis reports statistically significant changes in most listed laboratory parameters. The change in monocyte percentage was not statistically significant ($p=0.0563$).

Overall response

Table 6: Overall response to therapy.

Percentage relief	No. of patients	%
$\geq 75\%$	15	25.0
51–75%	30	50.0
25–50%	13	21.67
1–25%	2	3.33
No relief	0	0

Forty-five of 60 children (75%) demonstrated more than 50% overall relief according to the predefined response categories. No adverse effects were reported during the study period.

DISCUSSION

Kasa is described in Ayurveda as a disorder involving the respiratory system, with important contributions from Vata and Kapha. Classical descriptions of Kaphaja Kasa include increased secretions, anorexia, nausea, coryza and impaired digestive function.^[3] These features correspond with several of the clinical parameters evaluated in the present study.

The predominance of the 8–10-year age group and slight male predominance describe the characteristics of this recruited clinical sample; they should not be interpreted as evidence of age- or sex-specific susceptibility because of the limited sample size and absence of a comparator group.

The high frequency of reported Guru, Sheeta, Abhishyandi and Madhura dietary exposure is consistent with the Ayurvedic interpretation of Kapha aggravation. Exposure to dust and smoke was also reported among a substantial proportion of participants. These findings provide clinical context for the presentation observed in this study.

Kantakari Avaleha contains a combination of drugs traditionally used in respiratory disorders. Kantakari, Pippali, Maricha and Shunthi are described in Ayurvedic literature in relation to respiratory and digestive functions, while Guduchi and other ingredients contribute additional traditional properties.^[4,5] From an Ayurvedic perspective, the formulation may therefore be interpreted as addressing Kapha accumulation, impaired Agni and respiratory channel obstruction.

The present study demonstrated a 60.81% reduction in cough bouts per hour. Sleep disturbance, throat infection, sputum and other objective features also improved. Among subjective parameters, Mukha-Kantha Shushkata showed the greatest reported improvement (93.53%), followed by Jwara (89.47%) and Mandagni (89.39%).

The overall response distribution showed that 75% of children had more than 50% relief. However, because the study was open-label and lacked a comparator group, spontaneous improvement, regression to the mean, natural variation in recurrent symptoms and participant/observer expectation cannot be separated from the effect of the intervention.

The statistically significant pre- and post-treatment differences demonstrate change over time but do not independently establish causal efficacy. This is particularly important when evaluating recurrent paediatric respiratory symptoms, which can fluctuate naturally over time.^[1,2]

No adverse effects were reported during the 21-day observation period. This observation supports tolerability under the study conditions but is insufficient to establish long-term safety in children.

Overall, the findings provide preliminary clinical data supporting further evaluation of Kantakari Avaleha. Larger controlled studies with standardized outcomes, appropriate comparators, longer follow-up and clear documentation of formulation quality are needed.

LIMITATIONS

- Small sample size of 60 children.
- Open-label, single-arm design without a placebo or active comparator.
- Short treatment/observation period and limited assessment of recurrence.
- Potential participant and observer expectation bias.
- Heterogeneous clinical presentation of recurrent cough, limiting extrapolation to specific respiratory diagnoses.
- The thesis contains differing dose descriptions in different sections; the final administered dose should be verified against the original protocol/CRF before submission.

CONCLUSION

Kantakari Avaleha administration was associated with improvement in subjective and objective clinical parameters of Kasa among the 60 children aged 5–12 years enrolled in this open-label single-arm study. Reductions were observed in cough frequency, sleep disturbance, throat infection, wheezing, crepitations and sputum, with improvement also documented in associated symptoms. No adverse effects were reported during the study period. Because the study lacked a comparator group and had a limited sample and follow-up, the findings should be regarded as preliminary. Larger controlled comparative studies are required to determine the independent therapeutic effect and longer-term safety of Kantakari Avaleha in paediatric Kasa.

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AUTHOR CONTRIBUTION

Arati Amarnath Yadav: conceptualization, study design, patient recruitment, clinical assessment, intervention administration, data collection, statistical analysis, interpretation of findings and manuscript preparation. Prof. (Dr.) Ritesh M. Kela: supervision, methodological guidance, academic review, interpretation of findings and critical revision of the manuscript. Both authors approved the final manuscript for submission.

DECLARATIONS

Ethical approval: Institutional Ethics Committee approval was obtained (IEC No. 2023/36/2026), as recorded in the dissertation.

Informed consent: Written informed consent was obtained from the parents/legal guardians of participating children.

Clinical trial registration: The dissertation states that CTIR registration was obtained before enrolment. The exact registration number must be inserted from the official record before submission.

Conflict of interest: The author declares no conflict of interest related to this study.

Funding: No external funding was reported for the study.

Data availability: The underlying study records are held by the investigators and institution and may be made available to the journal/editor in accordance with institutional and ethical requirements.

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