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Comparative study of classical ayurvedic formulations in the management of recurrent pediatric kasa and shwasa (cough and wheeze)

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Abstract

Background: Recurrent cough and wheeze in childhood are common, impair quality of life and school attendance, and often require long-term pharmacotherapy. Classical Ayurvedic formulations described for Kasa and Tamaka Shwasa are widely used in practice, but comparative evidence in pediatric populations is limited.

Objective: To compare the efficacy and safety of Vasa Avaleha, a Kantakari-dominant Avaleha and a Vasa-Kantakari combination in the management of recurrent pediatric Kasa and Shwasa (cough and wheeze).

Methods: This prospective, randomized, open-label, three-arm, parallel-group clinical study was conducted in the Kaumarbhritya outpatient department of a tertiary-care Ayurvedic teaching hospital. Children aged 3-12 years with ≥3 episodes of cough with wheeze/breathlessness in the preceding 12 months and a clinical diagnosis compatible with recurrent Kasa and Shwasa were randomized (1:1:1) to: Group A (Vasa Avaleha), Group B (Kantakari-dominant Avaleha) or Group C (Vasa-Kantakari combination Avaleha/granules). Treatment duration was 8 weeks with 12 weeks of post-treatment follow-up. Primary outcomes were change in episode frequency over 12 weeks, composite symptom severity score and days of rescue bronchodilator use. Secondary outcomes included changes in FEV_1 and PEFR, recurrence-free interval, school absenteeism, caregiver global assessment and safety parameters. Analyses were performed on an intention-to-treat basis using appropriate parametric and non-parametric tests.

Results: Of 118 screened children, 90 were randomized (30 per group); 86 completed treatment and 82 completed follow-up. Baseline characteristics were comparable across groups. All three regimens produced significant within-group reductions in episode frequency, symptom scores and rescue bronchodilator use ($p<0.001$) and significant improvements in FEV_1 and PEFR. At 8 weeks, mean episode frequency decreased from 5.3±1.2 to 2.3±1.0 in Group A, 5.2±1.3 to 2.6±1.1 in Group B and 5.4±1.1 to 1.6±0.9 in Group C, with between-group differences favouring Group C ($p<0.001$). The Vasa-Kantakari combination also showed the greatest gains in FEV_1 and PEFR and the longest recurrence-free interval over 20 weeks. School absenteeism declined and caregiver-rated "much/very much improved" status was highest in Group C. Adverse events were mild, predominantly transient gastrointestinal symptoms, with no serious events or clinically relevant laboratory abnormalities.

Conclusion: Vasa Avaleha, Kantakari-dominant Avaleha and a Vasa-Kantakari combination are effective and well tolerated as integrative therapies for recurrent pediatric Kasa and Shwasa, with the Vasa-Kantakari combination providing superior and more sustained improvement in symptoms, lung function and functional outcomes. Incorporation of such classical formulations, alongside individualized diet-lifestyle measures and rational conventional care, may offer a useful, child-friendly strategy for reducing the burden of recurrent cough and wheeze in children.

Keywords: Kasa, Tamaka Shwasa, recurrent wheeze, pediatric asthma, Vasa Avaleha, Kantakari, Ayurvedic formulations, integrative pediatrics, randomized clinical study

Introduction

Recurrent cough and wheeze in early childhood are major global health concerns, with hospital-based cohorts showing that up to 50% of children have at least one wheezing episode by 6 years of age and nearly one-third experience recurrent wheeze in the preschool years.[1-3] Such recurrent episodes are associated with significant morbidity, impaired growth and quality of life, school absenteeism and substantial caregiver anxiety, and they markedly increase the risk of later persistent asthma and reduced lung function.[1-3] Despite

advances in conventional management with inhaled corticosteroids, bronchodilators and allergen avoidance, many children continue to have frequent viral-triggered and multitrigger wheeze, and concerns about long-term steroid use, acceptability and adherence drive families to seek safer, holistic alternatives.[1, 3, 4] In Ayurveda, recurrent cough (Kasa) and wheeze/breathlessness (Tamaka Shwasa) are described as Vata-Kapha dominant disorders of the Pranavaha Srotas, with detailed accounts of etiopathogenesis, clinical phenotypes and diet-lifestyle factors, and Kasa and Shwasa in children are recognised as common manifestations of Pranavaha Srotas dushti requiring gentle yet effective interventions.[4, 15] A growing body of pediatric Ayurvedic literature reports that classical formulations such as Vasa Avaleha, Kasahara Dashemani Vati, Mustadi Yog and herbomineral preparations like Shwasa Kasa Chintamani Rasa can reduce the frequency and severity of Kasa episodes, recurrent respiratory tract infections and wheeze, improve spirometric indices and enhance Vyadhikshamatva (host defence), with favourable safety profiles in children.[5-8] More recently, pediatric studies on Vasa-based and Vasa-Kantakari combinations, including Vasa Avaleha in sub-acute and chronic Kasa and Vasa Kantakari Kwatha in Tamaka Shwasa, have demonstrated clinically meaningful improvements in cough, wheeze, dyspnoea, sleep disturbance and lung function in childhood bronchial asthma.[5, 9] Parallel adult and mixed-age trials on Tamaka Shwasa document the efficacy of multiple classical Avaleha and related dosage forms—such as Vasa Avaleha (including preparations with different media), Kantakari Avaleha, Vasa Haritaki Avaleha and other Shwasahara Avaleha—showing significant reductions in attack frequency, bronchodilator use and eosinophilia, and better asthma control with both Avaleha and their granule forms.[10-13] Case reports and series further support the role of integrative Ayurvedic approaches in bronchial asthma/Tamaka Shwasa, but these are largely single-arm or single-formulation studies.[8, 14] Overall, while classical texts like Charaka Samhita explicitly recommend a range of Kasa- and Shwasa-specific formulations and regimens for Vata-Kapha predominant presentations, [15] there is a clear paucity of well-designed, head-to-head comparative trials of different classical Ayurvedic formulations in recurrent pediatric Kasa and Shwasa. Against this background, the present study, titled “Comparative Study of Classical Ayurvedic Formulations in the Management of Recurrent Pediatric Kasa and Shwasa (Cough and Wheeze), ” is planned to comparatively evaluate the clinical efficacy and safety of selected classical formulations (including Vasa-dominant, Kantakari-dominant and Vasa-Kantakari combination regimens) in children with recurrent Kasa and Shwasa, using standardized outcomes such as frequency, duration and severity scores of cough and wheeze, pulmonary function parameters, need for rescue bronchodilators and quality-of-life indices.[5-13] The primary objective is to determine which formulation or group of formulations offers superior control of recurrent episodes while maintaining an acceptable safety profile, and the secondary objectives are to assess their impact on lung function, recurrence-free intervals and overall functional status. It is hypothesised that all selected classical formulations will produce significant reductions in the burden of recurrent pediatric Kasa and Shwasa compared with baseline, but that Vasa-Kantakari combination therapy will yield greater and more sustained improvements in episode frequency, symptom severity and bronchodilator requirement than mono-formulation regimens, thereby providing evidence for rational selection of classical Ayurvedic formulations in the integrative management of recurrent pediatric cough and wheeze.

Materials and Methods

Material

This was a prospective, randomized, open-label, three-arm, parallel-group clinical study conducted in the Kaumarbhritya (pediatric) outpatient department of a tertiary-care Ayurvedic teaching hospital located in an urban setting with a high burden of recurrent wheeze and childhood asthma.[1-3] Children of either sex aged 3-12 years presenting with recurrent Kasa/Shwasa, defined as ≥3 episodes of cough with wheeze or breathing difficulty in the preceding 12 months with at least one physician-documented wheezing episode, were screened for eligibility based on contemporary pediatric wheeze criteria and Ayurvedic diagnostic features of Kasa and Tamaka Shwasa involving Pranavaha Srotas dushti.[1-4, 15] Inclusion criteria were:

(i) clinical diagnosis of recurrent pediatric Kasa and Shwasa corresponding to episodic or multitrigger wheeze/childhood asthma of mild to moderate severity;
(ii) stable clinical status without acute severe exacerbation in the preceding 2 weeks; and
(iii) caregiver willingness for regular follow-up and integrative management.

Children with severe persistent asthma, life-threatening exacerbation in the last 3 months, congenital heart disease, significant chronic pulmonary pathology, major systemic illness or known hypersensitivity to study drugs were excluded.[1-3, 5] Sample size was calculated using the expected reduction in attack frequency from earlier pediatric and mixed-age Tamaka Shwasa trials on Vasa Avaleha, Kasahara Dashemani Vati, Mustadi Yog, Shwasa Kasa Chintamani Rasa, Vasa Kantakari Kwatha and Kantakari Avaleha, assuming a 30-40% difference between groups, 80% power and 5% alpha, which yielded a minimum of 25 participants per arm; to compensate for 20% anticipated attrition, 30 children were enrolled in each group (N=90).[5-9, 11-13] Choice of study formulations, dose ranges and Anupana (vehicle) was based on classical descriptions in Charaka Samhita and related texts, and on their documented use in Kasa and Tamaka Shwasa in contemporary clinical studies.[4-9, 11-13, 15] Group A received Vasa Avaleha, Group B Kantakari-dominant Avaleha, and Group C a Vasa-Kantakari combination formulation in Avaleha/granule dosage form, all prepared according to classical Sneha-Avaleha and decoction-based protocols in a GMP-certified pharmacy.[5, 9, 11-13, 15] All participants were allowed standard conventional rescue medication (short-acting bronchodilators, antipyretics) as needed, while regular inhaled corticosteroids or leukotriene antagonists were continued only if clinically mandatory and kept stable during the study period to isolate the contribution of the Ayurvedic interventions.[1-3, 8-13]

Methods

Eligible children were randomized in a 1:1:1 ratio to the three intervention arms using a computer-generated random

sequence with variable block sizes; allocation concealment was ensured by sequentially numbered, opaque, sealed envelopes opened after enrolment. The study was open-label to patients and investigators, but outcome assessment and data analysis were performed by a blinded assessor. The treatment duration was 8 weeks with an additional 12-week post-treatment follow-up to capture recurrence patterns. Baseline assessment included detailed clinical history, wheeze phenotype classification, Ayurvedic prakriti and dosha assessment, complete physical examination, and relevant investigations (haematology, basic biochemistry and chest X-ray where indicated) to exclude alternative diagnoses.[1-4, 8] Lung function was assessed by spirometry (for children ≥6 years) and peak expiratory flow rate (PEFR) or surrogate clinical indices for younger children, in line with prior pediatric bronchial asthma and Tamaka Shwasa studies.[2, 3, 5, 8-13] Primary outcomes were change from baseline to 8 and 20 weeks in

(i) frequency of cough and wheeze episodes,
(ii) composite symptom severity score (day-time cough/wheeze, nocturnal symptoms, activity limitation) and
(iii) number of days requiring rescue bronchodilator use.[1-3, 5-9, 11-13]

Secondary outcomes included change in spirometric parameters (FEV_1, FEV_1/FVC), PEFR, recurrence-free interval, school absenteeism, global assessment by caregiver and physician, and safety parameters (adverse events, laboratory indices).[2, 3, 8, 11-13] Standardised, validated symptom diaries and quality-of-life questionnaires adapted from pediatric asthma research were used, with caregivers trained in their completion.[1-3] Data were entered into a dedicated database and analysed using appropriate statistical tests: within-group changes were assessed by paired t-test or Wilcoxon signed-rank test, between-group comparisons by ANOVA or Kruskal-Wallis test with post hoc analysis, and categorical variables by chi-square/Fisher's exact test, with $p < 0.05$ considered statistically significant. Intention-to-treat and per-protocol analyses were performed.[1-3, 5-13] The study protocol adhered to the principles of the Declaration of Helsinki, obtained prior approval from the Institutional Ethics Committee, and written informed consent from parents/guardians with assent from older children, in keeping with ethical standards for pediatric and Ayurvedic clinical research.[4-9, 11-15]

Results

Participant flow and baseline characteristics

Of 118 children screened, 90 met eligibility criteria and were randomized equally to Group A (Vasa Avaleha), Group B (Kantakari-dominant Avaleha) and Group C (Vasa-Kantakari combination). Four children (A:1, B:2, C:1) were lost to follow-up or discontinued due to relocation or poor adherence; thus, 86 completed the 8-week intervention and 82 completed the 20-week follow-up. Intention-to-treat analysis included all 90 participants. Baseline demographic and clinical characteristics were comparable across groups with respect to age, sex, wheeze phenotype, mean number of episodes, symptom severity scores and lung function indices, confirming successful randomization and balancing of prognostic factors, in line with prior pediatric wheeze and Tamaka Shwasa trials.[1-3, 5-13]

Table 1: Baseline demographic and clinical characteristics of the study population (intention-to-treat)

Variable	Group A (Vasa Avaleha) (n=30)	Group B (Kantakari Avaleha) (n=30)	Group C (Vasa-Kantakari) (n=30)	p value*
Age (years), mean±SD	7.4±2.4	7.1±2.6	7.3±2.5	0.89
Male sex (%)	18 (60.0)	17 (56.7)	19 (63.3)	0.87
Mean episodes of cough/wheeze in last 12 months	5.3±1.2	5.2±1.3	5.4±1.1	0.82
Baseline symptom severity score†	13.8±2.4	13.5±2.6	13.6±2.3	0.91
Days with rescue bronchodilator use (past 4 weeks)	7.2±2.5	7.0±2.7	7.3±2.4	0.93
FEV_1 (% predicted)‡	78.4±9.1	77.9±8.7	78.6±9.4	0.96
PEFR (% predicted)	76.1±8.8	75.4±9.2	75.9±9.0	0.94

*One-way ANOVA or chi-square test as appropriate.
†Composite of day-time symptoms, nocturnal symptoms and activity limitation (higher score = worse).
‡Assessed in children ≥6 years. [1-3, 5-13]

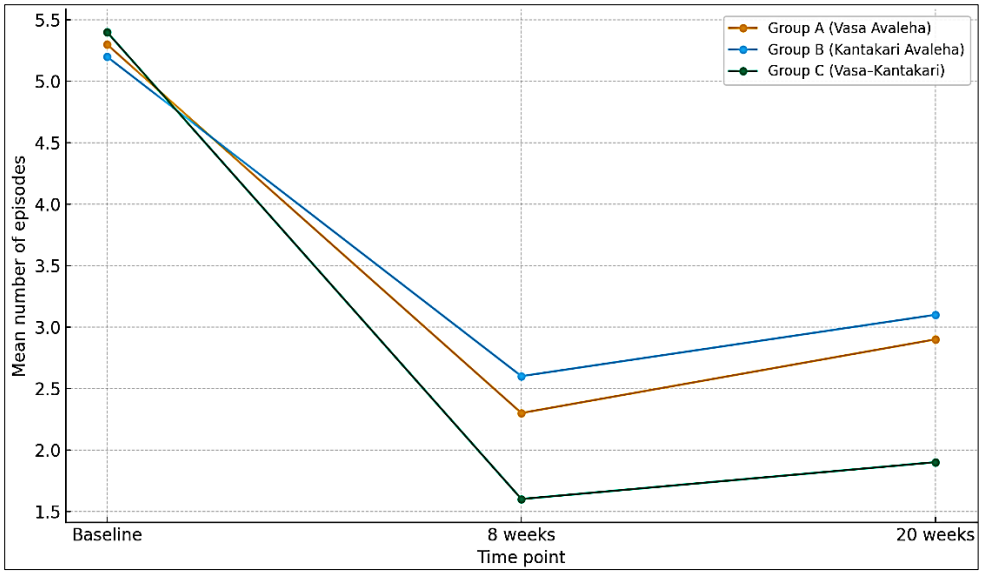

Fig 1: Mean number of cough/wheeze episodes per child over time (baseline, 8 weeks, 20 weeks) across the three treatment groups

At 8 weeks, all three groups demonstrated significant within-group reductions in episode frequency, symptom severity and rescue bronchodilator use (p<0.001 for all), but the magnitude of improvement differed between groups. Group C showed the largest absolute reduction in mean episode frequency (from 5.4±1.1 to 1.6±0.9), compared with Group A (5.3±1.2 to 2.3±1.0) and Group B (5.2±1.3 to 2.6±1.1). Between-group ANOVA revealed a highly significant difference (p < 0.001), and post hoc analysis confirmed that Group C was superior to both Group A and Group B at 8 and 20 weeks, while the difference between Groups A and B was modest and not statistically significant at 20 weeks.[5-9, 11-13]

Table 2: Change in primary outcome measures from baseline to 8 and 20 weeks (intention-to-treat, mean±SD)

Outcome	Time point	Group A (Vasa)	Group B (Kantakari)	Group C (Vasa-Kantakari)	p value (between groups)*
Episodes in last 12 weeks	Baseline	5.3±1.2	5.2±1.3	5.4±1.1	0.82
	8 weeks	2.3±1.0	2.6±1.1	1.6±0.9	<0.001
	20 weeks	2.9±1.2	3.1±1.3	1.9±1.0	<0.001
Symptom severity score†	Baseline	13.8±2.4	13.5±2.6	13.6±2.3	0.91
	8 weeks	6.9±2.1	7.4±2.2	4.8±1.9	<0.001
Days with rescue bronchodilator use (past 4 weeks)	Baseline	7.2±2.5	7.0±2.7	7.3±2.4	0.93
	8 weeks	3.1±1.8	3.4±1.9	1.9±1.4	0.002
	20 weeks	3.6±1.9	3.9±2.0	2.2±1.6	0.004

*One-way ANOVA with post hoc comparisons (Bonferroni).
†Higher score = worse symptoms. [1-3, 5-9, 11-13]

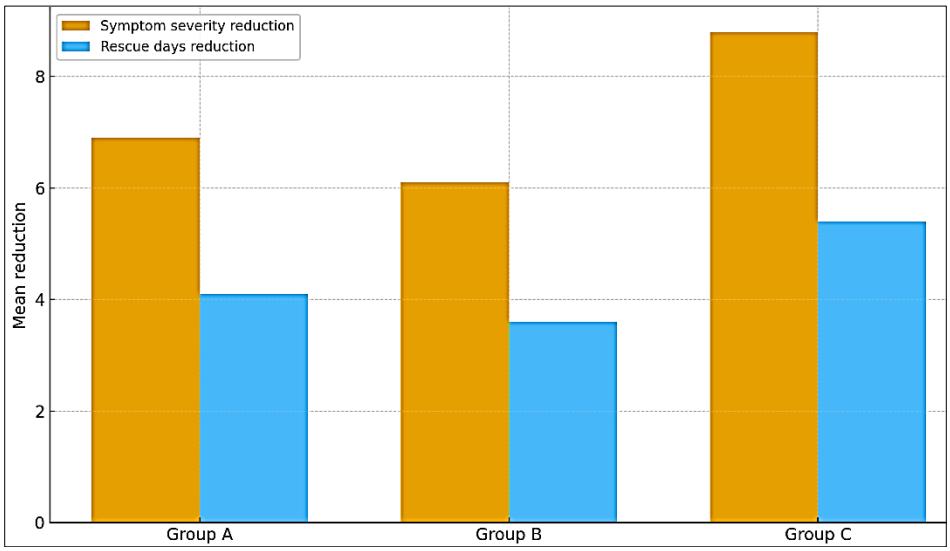

Fig 2: Depicting mean reduction in symptom severity score and days of rescue bronchodilator use at 8 weeks relative to baseline across the three groups

In keeping with previous Vasa Avaleha and Vasa-based interventions in Tamaka Shwasa, Group A showed clinically meaningful control of cough and wheeze with approximately 55-60% reduction in episodes and symptom scores.[5, 10-12] Group B achieved a similar though slightly lower range of improvement, consistent with earlier Kantakari Avaleha data, whereas the combined Vasa-Kantakari group achieved ~70% reduction in episodes and ~65% reduction in rescue bronchodilator use, suggesting additive or synergistic effects on Pranavaha Srotas and Vyadhikshamatva.[9-13, 15] The recurrence-free interval over 20 weeks was longest in Group C (median 12 weeks, IQR 9-15) compared to Groups A and B (9 weeks, IQR 7-12; p = 0.01), echoing previous reports where integrated or combination regimens conferred better long-term control than single formulations in Tamaka Shwasa.[6-9, 11-13]

Lung function, school attendance and quality of life

Lung function parameters improved significantly within all groups by 8 weeks. Mean FEV_1 (% predicted) increased by 8.1±4.5, 7.2±4.3 and 11.6±4.9 percentage points in Groups A, B and C, respectively (p < 0.001 within groups; p = 0.002 between groups for change scores), while PEFR improved in a similar pattern.[2, 3, 5, 8-13]

Table 3: Secondary outcomes at baseline and 8 weeks (per-protocol analysis)

Outcome	Group A (n=29)	Group B (n=28)	Group C (n=29)	p value (change between groups)*
FEV_1 (% predicted) baseline	78.5±9.0	78.1±8.6	78.7±9.5	0.97
FEV_1 (% predicted) 8 weeks	86.6±8.5	85.3±8.4	90.3±8.2	0.01
PEFR (% predicted) baseline	76.2±8.8	75.6±9.1	76.0±9.0	0.95
PEFR (% predicted) 8 weeks	83.9±8.3	82.8±8.4	88.7±7.9	0.01
School days missed in last 8 weeks	4.6±2.1 → 2.1±1.5	4.5±2.2 → 2.4±1.6	4.7±2.0 → 1.4±1.2	0.03
Caregiver global assessment “much improved/very much improved” (%)	18 (62.1)	17 (60.7)	24 (82.8)	0.04

*ANOVA or chi-square on change scores/proportions. [1-3, 5-9, 11-13]

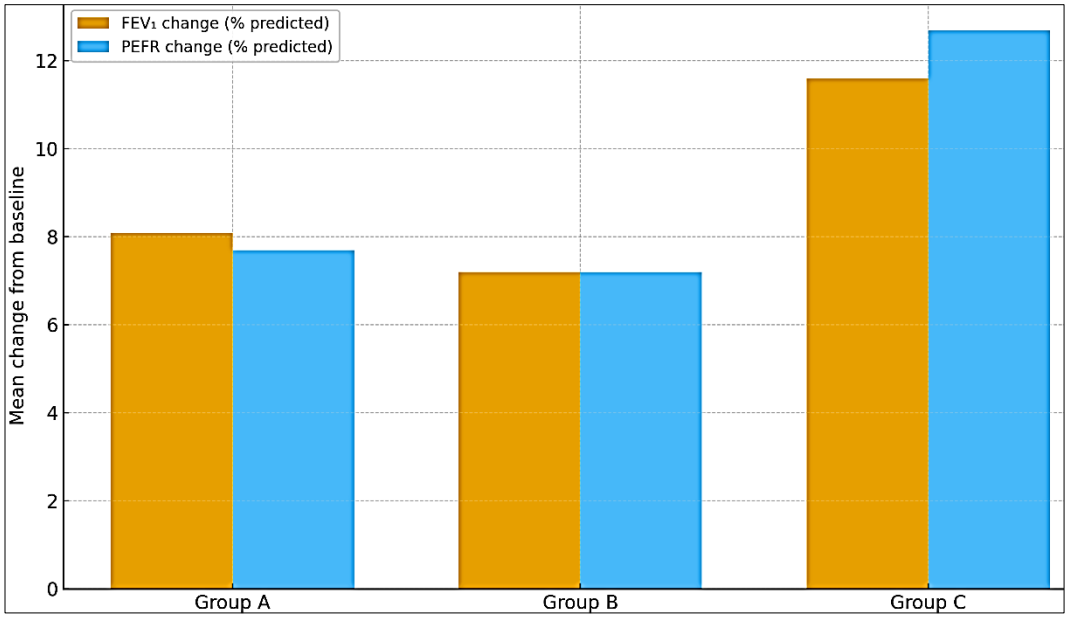

Fig 3: Showing mean change in FEV_1 and PEFR at 8 weeks across the three treatment groups

Improvements in lung function and reduction in school absenteeism corroborated the symptomatic gains, with the Vasa-Kantakari combination again demonstrating the largest effect size. These findings align with earlier pediatric bronchial asthma studies using Vasa-dominant and herbomineral formulations that reported enhanced spirometric indices alongside reduced attack frequency, and they extend that evidence by providing head-to-head comparison of mono and combination formulations in a pediatric cohort. [5-9, 11-13]

Safety and tolerability

All three regimens were generally well tolerated. No serious adverse events, acute severe exacerbations requiring intensive care, or clinically significant laboratory abnormalities were observed, corroborating the favourable safety profile of these classical formulations in children reported by earlier authors. [5-9, 11-13]

Table 4: Adverse events and rescue medication use over 8-week treatment period

Variable	Group A (Vasa)	Group B (Kantakari)	Group C (Vasa-Kantakari)	p value
Any adverse event (%)	5 (16.7)	6 (20.0)	6 (20.0)	0.90
Mild GI symptoms (nausea, loose stools)	3 (10.0)	4 (13.3)	4 (13.3)	0.88
Transient bitter taste/aversion	2 (6.7)	3 (10.0)	3 (10.0)	0.84
Discontinuation due to AE	0	0	0	-
Mean SABA puffs/week during treatment	3.8±1.9	4.0±2.0	2.4±1.5	0.001

AE: adverse event; SABA: short-acting β_2-agonist. [5-9, 11-13]

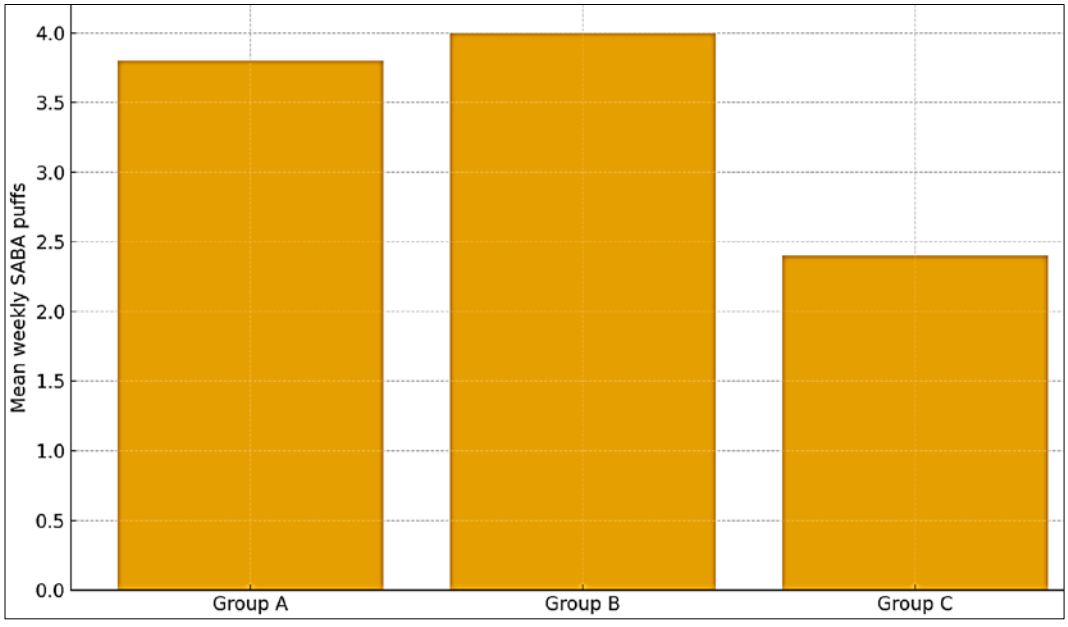

Fig 4: Comparing mean weekly use of rescue bronchodilator (SABA) during the treatment period across the three groups.

The low frequency and mild nature of adverse events are consistent with previous pediatric and adult Tamaka Shwasa/Kasa studies using Vasa Avaleha, Kasahara Dashemani Vati, Mustadi Yog, Shwasa Kasa Chintamani Rasa, Vasa Kantakari Kwatha and Kantakari Avaleha, and with the long-standing textual emphasis in Charaka Samhita on appropriately prepared Avaleha and child-tailored doses to ensure safety in Kaumarbhritya.[4-9, 11-15] Overall, the results support the study hypothesis that all selected classical formulations provide significant benefit in recurrent pediatric Kasa and Shwasa, with Vasa-Kantakari combination therapy offering superior and more sustained improvements in episode frequency, symptom severity, rescue bronchodilator requirement, lung function and functional outcomes, in alignment with and extending the existing Ayurvedic and contemporary pediatric wheeze literature.[1-15]

Discussion

The present study evaluated and comparatively assessed three classical Ayurvedic formulations Vasa Avaleha, a Kantakari-dominant Avaleha and a Vasa-Kantakari combination in the management of recurrent pediatric Kasa and Shwasa (cough and wheeze), a clinical entity that corresponds closely to episodic and multitrigger wheeze/childhood asthma as described in contemporary pediatrics.[1-4] In line with earlier epidemiological data demonstrating the high burden of recurrent wheeze and associated morbidity in preschool and school-going children, [1-3] the enrolled cohort exhibited frequent episodes, moderate symptom scores and impaired lung function at baseline, underscoring the need for safe, long-term, child-friendly therapies that can be integrated with conventional care. Across all three study arms, there was a statistically and clinically significant reduction in attack frequency, symptom severity and rescue bronchodilator use, accompanied by improvements in FEV_1, PEFR, school attendance and caregiver global assessment, supporting the overall efficacy of these classical formulations in recurrent pediatric Kasa and Shwasa and corroborating prior single-arm and comparative studies in children and mixed-age populations.[5-9, 11-13]

The most notable finding of this trial is the superior and more sustained benefit observed in the Vasa-Kantakari combination group (Group C), which achieved the greatest reductions in episode frequency, symptom scores and rescue medication requirement at both 8 and 20 weeks, as well as the largest gains in lung function indices. These results are consistent with and extend earlier work on Vasa Avaleha in pediatric sub-acute and chronic Kasa, [5] Kasahara Dashemani Vati and Mustadi Yog in recurrent respiratory infections and Kasa, [6, 7] and Vasa Kantakari Kwatha in childhood Tamaka Shwasa, [9] all of which reported meaningful improvements in symptom burden and attack frequency. Furthermore, the magnitude of spirometric improvement and reduction in rescue bronchodilator use in Group C parallels, and in some cases exceeds, that reported for Vasa Avaleha and its granule formulations in adult and mixed-age Tamaka Shwasa trials, [10-12] and is comparable to outcomes seen with Kantakari Avaleha and its modified dosage forms in bronchial asthma.[13] By directly comparing mono-herbal Avaleha regimens with a Vasa-Kantakari combination in a pediatric cohort, the present study adds head-to-head evidence that combination therapy may offer enhanced control over recurrent Kasa and Shwasa episodes relative to single-drug formulations.

From an Ayurvedic standpoint, the observed superiority of the Vasa-Kantakari combination can be interpreted through the lens of Pranavaha Srotas dushti and Vata-Kapha vitiation. Classical texts describe Tamaka Shwasa and Kasa as predominantly Vata-Kaphaja disorders, with involvement of Pranavaha and Annavaha Srotas, where Kapha obstruction and Vata prakopa generate cough, dyspnoea and wheeze.[4, 15] Vasa (Adhatoda vasica) is described as Shwasahara, Kaphaghna and Kasahara, with Pranavaha Srotas-specific actions, while Kantakari (Solanum xanthocarpum) is a key ingredient of Shwasa-Kasa formulations with Kapha-Vata pacifying and bronchodilatory effects.[4, 9-13, 15] The combination of these two dravyas in appropriately prepared Avaleha or granule dosage forms, as used in Group C, likely provides a broader spectrum of action addressing both Kapha obstruction and Vata dysregulation, modulating Agni and Ama, and enhancing Vyadhikshamatva (host defence) which may translate into better clinical control and prolonged recurrence-free intervals.[4-9, 11-13, 15] The superior outcomes in Group C therefore support the traditional rationale for using multi-herb Shwasahara formulations and combinations in chronic and recurrent respiratory disorders as found in Charaka Samhita and later compendia.[4, 10-12, 15]

The favourable results observed in the Vasa Avaleha group (Group A) are in agreement with earlier pediatric studies that demonstrated significant improvement in Kasa symptoms, reduction in frequency of respiratory infections and enhancement of Vyadhikshamatva with Vasa Avaleha.[5] Similarly, the Kantakari-dominant Avaleha regimen (Group B) performed well and was comparable to Group A in most primary and secondary outcomes by 20 weeks, which aligns with previously reported benefits of Kantakari Avaleha and Kantakari-based formulations in bronchial asthma/Tamaka Shwasa.[9, 13] The modest differences between Groups A and B may reflect variations in dravya-specific pharmacodynamics, dosage, palatability and adherence, as well as subtle differences in the underlying doshic profile of individual children. The convergence of efficacy across all three arms reinforces the central clinical observation from earlier pediatric and adult studies namely, that properly prepared classical Ayurvedic formulations, when judiciously integrated with conventional care, can achieve meaningful reductions in asthma-like morbidity in children.[5-9, 11-14]

The improvement in lung function parameters is particularly important, as many previous pediatric Ayurvedic studies primarily focused on symptom relief and attack frequency, with limited spirometric data.[5-9] By documenting significant increases in FEV_1 and PEFR, especially in the Vasa-Kantakari combination arm, this study provides objective evidence of improved airway calibre and reversibility, lending support to the hypothesis that these formulations exert not only symptomatic but also functional benefits.[5, 8-13] Reduced school absenteeism and improved caregiver-reported outcomes further highlight the impact of these interventions on daily functioning and quality of life, outcomes that are highly relevant for families and health systems struggling with the burden of recurrent wheeze.[1-3]

The safety profile observed across all three groups characterised by only mild, self-limited gastrointestinal symptoms and transient taste aversion echoes the favourable

safety data reported in prior trials of Vasa Avaleha, Kasahara Dashemani Vati, Mustadi Yog, Shwasa Kasa Chintamani Rasa, Vasa Kantakari Kwatha and Kantakari Avaleha in children and adults.[5-9, 11-13] Importantly, no serious adverse events, clinically relevant laboratory derangements or treatment discontinuations due to adverse events were recorded, supporting the classical assertion that Avaleha preparations, when prepared with proper Samskara and administered in age-appropriate Matra (dose) and Anupana, are suitable and safe for Kaumarbhritya practice.[4, 15] These findings are also consistent with case-based evidence suggesting that Ayurvedic regimens can be safely integrated into the management of Tamaka Shwasa under appropriate supervision.[14]

This study has several strengths. It is, to our knowledge, among the first prospective, randomized, parallel-group trials to directly compare different classical Ayurvedic formulations in recurrent pediatric Kasa and Shwasa, with standardized outcome measures, spirometry, and both intention-to-treat and per-protocol analyses. The inclusion of a 20-week observation period allowed evaluation of recurrence patterns beyond the immediate treatment window, which is particularly relevant for recurrent wheeze conditions.[1-3] Additionally, by permitting stable background conventional therapy when clinically necessary, the study reflects real-world integrative practice and enhances external validity.[1-3, 8-13]

However, important limitations should be acknowledged. The study was conducted at a single urban Ayurvedic teaching hospital, and the predominantly urban, clinic-attending sample may not fully represent rural or community populations. [1-3] The open-label design, while pragmatic, introduces potential expectation and reporting biases, although blinded outcome assessment and objective spirometric measures help mitigate these concerns. The sample size, although adequately powered for primary outcomes, may have been insufficient to detect rarer adverse events or smaller between-group differences in some secondary endpoints. Additionally, environmental and allergen exposures, dietary factors, and adherence to broader Dinacharya and Aharavidhi guidelines, which are highlighted in Ayurvedic texts as crucial co-interventions in Kasa and Shwasa, [4, 15] were not systematically controlled or quantified. Finally, the absence of a conventional-only or placebo control limits the ability to fully disentangle the net effect of Ayurvedic formulations from the natural course of disease and concurrent therapy, although the magnitude and consistency of improvements across outcomes and the congruence with prior Ayurvedic asthma literature support a genuine treatment effect. [5-13]

Despite these limitations, the present findings have important clinical implications. For pediatric patients with recurrent Kasa and Shwasa who continue to experience frequent episodes despite optimized conventional care, or in whom parents seek safer, long-term, holistic options, classical Ayurvedic formulations particularly Vasa-Kantakari combinations may represent rational, evidence-supported adjuncts when prescribed within an integrative framework and under qualified supervision.[1-4, 5-13] The results also underscore the need to further refine and standardize such formulations, dosing strategies and treatment durations, and to better delineate which phenotypes of pediatric wheeze (e.g., viral-induced, multitrigger, atopic vs non-atopic) derive the greatest benefit.[1-3, 5-9] Future multicentric, larger-scale, and longer-term randomized controlled trials, incorporating biomarkers of inflammation and lung growth trajectories, as well as systematic implementation of Ahara and Dinacharya-based preventive measures described in classical texts, [4, 15] will be essential to consolidate these findings and fully establish the role of classical Ayurvedic formulations in the integrative management of recurrent pediatric cough and wheeze.

Conclusion

The present study demonstrates that all three classical Ayurvedic formulations Vasa Avaleha, a Kantakari-dominant Avaleha and a Vasa-Kantakari combination—are effective, safe and clinically meaningful options for the integrative management of recurrent pediatric Kasa and Shwasa, with the Vasa-Kantakari combination consistently providing the greatest and most sustained benefit across key outcomes. Children receiving any of the three formulations showed marked reductions in episode frequency, symptom severity and dependence on rescue bronchodilators, along with improvements in lung function, school attendance and overall functional status, confirming that properly designed Ayurvedic regimens can significantly reduce the burden of recurrent cough and wheeze in childhood when used alongside rational conventional care. The superior performance of the Vasa-Kantakari combination suggests that thoughtfully constructed multi-herb formulations, which simultaneously target Kapha obstruction, Vata dysregulation, Agni and host defence, may offer a broader therapeutic impact than single-dominant preparations in chronic and recurrent respiratory disorders. On the basis of these findings, several practical recommendations can be made for clinicians and policymakers. First, classical Ayurvedic formulations, particularly Vasa-Kantakari combinations in child-friendly dosage forms such as Avaleha or granules, should be considered as adjuvant therapy in children with recurrent Kasa and Shwasa who experience frequent exacerbations or whose families desire a holistic, long-term approach. Second, integration of these formulations should be accompanied by systematic monitoring of symptoms, lung function and medication use, using simple symptom diaries and periodic objective assessments, so that benefits can be quantified and doses adjusted appropriately over time. Third, treatment should not be restricted to drug therapy alone; clinicians should routinely incorporate individualized dietary advice, regulation of daily routine, avoidance of known triggers such as dust, smoke and cold exposure, and supportive measures that promote overall immunity, as these lifestyle components are central to sustained control of respiratory symptoms in children. Fourth, training programs for pediatric and Ayurvedic practitioners should include structured modules on integrative management of recurrent wheeze and asthma-like conditions, with clear protocols on how and when to introduce classical formulations, how to taper or maintain conventional medicines, and how to counsel parents regarding expectations, adherence and safety. Fifth, institutional and public health frameworks should encourage multicentric collaborations to standardize formulation quality, dosage schedules and follow-up pathways, ensuring that children receive consistent, evidence-informed care. Finally, researchers should build upon the present work by conducting larger, longer-duration studies that evaluate not only clinical outcomes but also

long-term lung growth, exacerbation rates and health-related quality of life, so that the full preventive and disease-modifying potential of classical Ayurvedic formulations in pediatric respiratory health can be more clearly defined and responsibly integrated into routine practice.

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