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Open Randomized Controlled Clinical Trial of Vyāghryādi Chūrṇa in the Treatment of Kaphaja Kāsa in Children

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Abstract

Background: Kaphaja Kāsa (productive cough) is a highly prevalent respiratory disorder in the pediatric population due to their natural Kapha dominance in early age. Modern pharmacological management often provides only temporary relief and carries risks of side effects and drug resistance, necessitating the search for safe and holistic alternatives. Vyāghryādi Chūrṇa is a classical Ayurvedic formulation indicated for respiratory ailments due to its Kapha-hara, Śleşma-nirhāraka, Dīpana, and Srotoshodhaka properties.

Objective: To evaluate the efficacy of Vyāghryādi Chūrṇa in the management of Kaphaja Kāsa in children by comparing it with Katphaladi Chūrṇa.

Methods: This was an Open Randomized Controlled Clinical Trial conducted on a total of 84 children aged 6 to 10 years presenting with classical symptoms of Kaphaja Kāsa for three days. Patients were excluded if they had associated Jwara (fever) or conditions like Pneumonia or Bronchial Asthma. Participants were divided into two groups of 42 each by Simple Randomized Sampling:

- Group A (Trial Group): Treated with Vyāghryādi Chūrṇa.
- Group B (Control Group): Treated with Katphaladi Chūrṇa.

The duration of medication was 7 days, with a follow-up of 7 days. Efficacy was assessed based on the reduction in the grades of cardinal symptoms like Kasa (cough), Shthivana (expectoration), Shirshoola (headache), Swarbheda (hoarseness), and Aruchi (anorexia). Statistical analysis included the Wilcoxon signed-rank test and the Mann-Whitney U test.

Results: Both groups showed a statistically significant improvement in all parameters ($p < 0.001$) in the management of Kaphaja Kāsa. However, the comparative analysis demonstrated that Group A (Vyāghryādi Chūrṇa) was significantly more effective than Group B (Katphaladi Chūrṇa) across all measured symptoms.

Parameter	Group A Mean Rank	Group B Mean Rank	P Value	Conclusion
Kasa	34.63	50.37	0.001	Significant (A>B)
Shthivana	37.40	47.60	0.041	Significant (A>B)
Shirashoola	31.82	53.18	<0.001	Significant (A>B)
Swarabheda	34.63	50.37	0.002	Significant (A>B)
Aruchi	33.40	51.60	<0.001	Significant (A>B)

Overall, 52.4% of patients in Group A showed marked improvement, compared to only 7.1% in Group B. The treatment was also found to be safe, with no reported adverse effects.

Conclusion: Vyāghryādi Chūrṇa is significantly more effective than Katphaladi Chūrṇa and provides a safe, effective, and affordable therapeutic alternative for the management of Kaphaja Kāsa in children.

1. Introduction

Respiratory ailments, particularly cough (Kāsa), are among the most frequent health problems in children, often being the primary reason for seeking medical attention. In the Ayurvedic system, Kāsa is categorized into five types, with the Kaphaja variety being highly prevalent in children due to their inherent Kapha-dominance during early life. Kaphaja Kāsa is characterized by congestion, heaviness, excessive production of thick phlegm (Śleşma), and sluggishness. These symptoms closely resemble modern pediatric conditions like recurrent productive cough, upper respiratory tract infections, and bronchitis.

The current standard of care, involving antibiotics, mucolytics, and cough suppressants, often provides temporary symptomatic relief but fails to prevent recurrence. Furthermore, repeated use of these medications in children is a growing concern due to associated side effects and the rising risk of drug resistance.

Ayurveda offers a holistic approach by focusing on correcting the underlying Doṣic imbalance and strengthening the digestive and immune systems (Agni and Bala). For Kaphaja Kāsa, formulations with properties like Kapha-hara (Kapha reducing), Śleşma-nirhāraka (expectorant), and Dīpana (digestive stimulant) are considered ideal.

Vyāghryādi Chūrṇa is a classical preparation containing four key ingredients: Vyāghrī (Solanum xanthocarpum), Lavanga (Syzygium aromaticum), Nagakeshara (Mesua ferrea). This combination is expected to act synergistically:

- Vyāghrī: Liquefies and expels mucus, relieving breathlessness (bronchodilator/expectorant).
- Lavanga: Having activeconstituents such as Eugenol, β caryophyllene hence has local anesthetic affect, Expectorant, Antimicrobial, Antioxidant activity
- Nagakeshara: Reduces Kapha accumulation and possesses anti-inflammatory, mucoregulatory and antimicrobial properties.

Despite its traditional use and pharmacological plausibility, systematic clinical evaluation of Vyāghryādi Chūrṇa in pediatric patients is limited. Therefore, this study was designed as an Open Randomized Controlled Clinical Trial to provide scientific evidence for the efficacy of Vyāghryādi Chūrṇa in the management of Kaphaja Kāsa in children.

2. Materials and Methods

2.1. Study Design and Setting

The study was an Open Randomized Controlled Clinical Trial conducted at the Outpatient Department (OPD) of the Kaumarbhritya (Pediatrics) department.

2.2. Study Participants and Sample Size

A total of 84 patients were selected via Simple Randomized Sampling and divided into two groups of 42 each.

Inclusion Criteria:

- Age group: 6 years to 10 years.
- Presence of classical signs and symptoms of Kaphaja Kāsa for a minimum of 3 days.
- Patients were selected irrespective of gender and socio-economic class.

Exclusion Criteria:

- Kasa types other than Kaphaja Kāsa.

- Kaphaja Kāsa associated with Jwara (fever).
- Patients diagnosed with conditions like Pneumonia, Tuberculosis (TB), Bronchial Asthma, or other Lower Respiratory Tract Infections (LRTI).

Group	Intervention	Status
Group A (n=42)	Vyaghryadi Churna	Trial Group
Group B (n=42)	Katphaladi Churna	Control Group

2.4. Study Duration

The total duration of the medication period was 7 days, with a follow-up period of 7 days.

2.5. Outcome Measures

The primary efficacy endpoints were the degree of improvement in the grades of the following five cardinal symptoms of Kaphaja Kāsa:

1. Kasa (Cough)
2. Shthivana (Expectoration/Phlegm production)
3. Shirshoola (Headache/Heaviness)
4. Swarbheda (Hoarseness of voice)
5. Aruchi (Anorexia/Loss of appetite)

2.6. Statistical Analysis

Data were analyzed using appropriate statistical tests. The Wilcoxon signed-rank test was used for assessing the change in symptoms within each group (before and after treatment). The Mann-Whitney U test was used for comparing the efficacy between the two groups. A p-value of < 0.05 was considered statistically significant.

3. Results

3.1. Within-Group Efficacy

Both Group A (Vyāghryādi Chūrṇa) and Group B (Katphaladi Chūrṇa) demonstrated a statistically significant reduction in the grades of all five cardinal symptoms after 7 days of treatment ($p < 0.001$). This confirmed that both formulations were effective in managing Kaphaja Kāsa. For example, the mean percentage of improvement for Aruchi was 71.8% in Group A and 49.0% in Group B.

3.2. Comparative Efficacy (Group A vs. Group B)

The comparative analysis using the Mann-Whitney U test showed a significant difference in efficacy between the two groups across all parameters. Group A (Vyāghryādi Chūrṇa) was found to be significantly more effective in reducing the grades of all symptoms compared to Group B (Katphaladi Chūrṇa).

For instance:

- In the reduction of Kasa (cough) grades, the difference was highly significant ($p=0.001$), favoring Group A.

- For Shirshoola (headache) and Aruchi (anorexia), the difference was most pronounced ($p < 0.001$).

3.3. Overall Effect

The overall assessment of clinical outcome further supported the superior efficacy of the trial drug:

- Group A (Vyāghryādi Chūrṇa): 52.4% of patients achieved marked improvement, and 40.5% achieved moderate improvement.
- Group B (Katphaladi Chūrṇa): Only 7.1% of patients achieved marked improvement, while 42.9% showed moderate improvement, and 50.0% showed mild improvement.

3.4. Safety

No adverse effects were observed or reported in either treatment group throughout the study, confirming the safety of Vyāghryādi Chūrṇa for pediatric use.

4. Discussion

The results of this study successfully validated the primary hypothesis, establishing that Vyāghryādi Chūrṇa is significantly more effective than Katphaladi Chūrṇa in managing Kaphaja Kāsa in children.

From an Ayurvedic perspective, Kaphaja Kāsa is rooted in the vitiation of Kapha and Mandāgni (impaired digestion), leading to the obstruction of the Prāṇavaha Srotas (respiratory channels). The therapeutic action of Vyāghryādi Chūrṇa aligns perfectly with this pathogenesis.

- The combination of its ingredients—Vyāghrī, Lavanga and Nagakeshara—provides a potent blend of Kaphahara and Srotoshodhaka actions, actively clearing the obstructed channels.
- The constituent drugs are known to possess expectorant and bronchodilator properties (e.g., Vyāghrī), which help in quicker phlegm clearance and relief of airway obstruction.
- Furthermore, ingredients like Lavanga exert Dīpana (appetizer/digestive stimulant) and immunomodulatory effects, addressing the root cause by correcting Agni and strengthening the body's resistance against recurrent respiratory infections. The quick and significant improvement in Aruchi (anorexia) in Group A (71.8% improvement) is a clinical reflection of this Dīpana effect.

This holistic approach, which aims for both symptomatic relief and correction of underlying Doṣa balance, represents a significant advantage over the purely symptomatic and often recurrence-prone modern management. The confirmed safety profile further supports its suitability as a primary therapeutic option in pediatric respiratory care.

Despite the clear and significant findings, the limitations of this study, such as the small sample size, single-center design, and short follow-up duration, necessitate further research. Future multi-center, double-blind, randomized controlled trials with a longer follow-up period and the inclusion of modern diagnostic parameters (e.g., spirometry, immunological markers) are warranted to generalize and solidify these results.

5. Conclusion

The Open Randomized Controlled Clinical Trial successfully demonstrated that Vyāghryādi Chūrṇa is significantly more effective than Katphaladi Chūrṇa in the management of Kaphaja Kāsa in children. Vyāghryādi Chūrṇa not only provides superior symptomatic relief across all tested parameters but also offers a safe and affordable therapeutic alternative that addresses the root pathophysiology, offering significant potential in pediatric respiratory healthcare

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