RESEARCH PAPER

Clinical Evaluation of the Add-on Effect of Samvardhana Ghrita with Vakshuddhikara Choorna in the Management of Speech Delay in Children

Dr. Archana Byahatti[1], Dr. Durga Prasad Dash[2], Dr. Ravindra Kumar Arahunasi[3]

[1] PhD Scholar, Department of Kaumarabhritya, Sri Sri College of Ayurvedic Science and Research Hospital, Sri Sri University, Cuttack, Odisha, India. Email: archu.byahatti@gmail.com | ORCID: https://orcid.org/0000-0003-3904-2745

[2] Professor & HOD, Department of Kaumarabhritya, Sri Sri College of Ayurvedic Science and Research Hospital, Sri Sri University, Cuttack, Odisha, India. Email: durga.d@srisriuniversity.edu.in | ORCID: https://orcid.org/0000-0002-5291-2154

[3] Professor & HOD, Department of Kayachikitsa, Sanjeevini Ayurveda Medical College and Hospital, Hubli, Karnataka, India. Email: matarohit@gmail.com

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ABSTRACT

Speech delay is a significant developmental concern in India, with a prevalence of up to 17%. Untreated delays can lead to long-term cognitive and social difficulties. While Ayurvedic formulations like Vakshuddhikara Choorna and Samvardhana Ghrita are individually indicated for speech issues, their combined synergistic effect has not been systematically studied. To evaluate the efficacy and add-on effect of Samvardhana Ghrita as an Anupana (vehicle) to Vakshuddhikara Choorna in children with speech delay. A randomized, comparative clinical trial was conducted on 100 children (aged 2–10 years) diagnosed with speech delay. Group A (Trial) received Vakshuddhikara Choorna with Samvardhana Ghrita, and Group B (Control) received Vakshuddhikara Choorna with Honey for 60 days. Assessments were performed at baseline, 30, 60, and 90 days using eight subjective parameters. Both groups showed significant improvement ($p < 0.05$) in all parameters. Group A demonstrated superior results, with a higher percentage of change in key parameters like Speech Intelligibility (105.9% vs. 82.9%) and Expressive Vocabulary of New Words (80.0% vs. 72.0%). A significant intergroup difference was noted in the "Stimulus of Excitement and Happiness" parameter at day 30 ($p = 0.0329$), favoring Group A. The combination of Samvardhana Ghrita with Vakshuddhikara Choorna is more effective than Vakshuddhikara Choorna alone in managing speech delay in children. The add-on effect is evident in faster and more profound improvements in speech intelligibility, vocabulary acquisition, and social responsiveness.

Keywords: Speech Delay, Samvardhana Ghrita, Vakshuddhikara Choorna, Kaumarabhritya, Add-on Effect

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Introduction

Intelligible speech and language are fundamental markers of a child's overall development, cognitive ability, and social integration. Timely identification and intervention for speech and language delays are critical, as untreated difficulties can lead to persistent challenges. In India, developmental speech delay affects a significant proportion of young children, with a reported prevalence of up to 17% [1]. However, data on this subject remains limited, and a lack of early intervention can have severe long-term consequences. Evidence suggests that untreated speech and language delays persist into adulthood in 40-60% of cases, predisposing individuals to a higher risk of social, emotional, behavioral, and cognitive problems [2, 3]. In the contemporary pediatric landscape, speech disorders represent a growing clinical challenge influenced by a complex interplay of biological, environmental, and psychological factors. The ancient Indian medical system of Ayurveda offers a comprehensive framework for understanding and managing such developmental concerns. According to

Ayurveda, speech formation (Vakpravrutti) is a process that begins with the generation of sound waves from the umbilicus (Nabhi), which travel upward through channels (Srotas) to be articulated by the vocal cords [4]. Speech disorders are often attributed to the vitiation of Vata and Kapha doshas, causing an obstruction (Avarana) in these channels, leading to conditions like Mooka (dumbness) or other forms of dysarthria [5]. The role of Udana Vata, a subtype of Vata located in the chest (Uras), is specifically highlighted as the primary force responsible for the initiation, strength, and clarity of speech [6].Classical Ayurvedic texts provide various formulations for managing speech disorders. Vakshuddhikara Choorna, referenced in Ashtanga Hrudaya, is a compound powder comprising herbs like Vacha (Acorus calamus), Yashtimadhu (Glycyrrhiza glabra), and Pippali (Piper longum), known for their effects on the nervous system and the respiratory tract. Samvardhana Ghrita, a medicated ghee described in Kashyapa Samhita, is a complex formulation with ingredients like Bala (Sida cordifolia), Atibala (Abutilon indicum), and Khadira (Acacia catechu). It is traditionally used as a developmental tonic for children, particularly in conditions like Phakka Roga, which is correlated with cerebral palsy and often includes Mookatwa (dumbness) as a key symptom [7]. Acharya Kashyapa also emphasized the importance of Swara (voice) in diagnosis, stating that a person's Sara (essence/quality) can be understood by their voice [8].Previous research has individually validated the efficacy of these formulations. A study by Sharashchandra R. demonstrated that Vakshuddhikara Churna provided significant relief in stuttering symptoms [9]. Another study by Meena M.K. found that Samvardhana Ghrita, when used as part of a therapy protocol, enhanced the achievement of speech and language milestones in children with cerebral palsy [10]. However, the potential synergistic or "add-on" effect of using Samvardhana Ghrita as an Anupana (vehicle) for Vakshuddhikara Choorna has not been explored. This study aims to bridge this gap by evaluating the combined efficacy of this novel treatment strategy in children with speech delay.

Objectives

- To evaluate the efficacy of Samvardhana Ghrita with Vakshuddhikara Choorna in the management of speech delay in children.
- To evaluate the combined efficacy of Samvardhana Ghrita with Vakshuddhikara Choorna over Vakshuddhikara Choorna alone in the management of speech delay in children.
- To assess the safety and tolerability of the combined intervention.

Literature Review

The conceptual understanding of speech in Ayurveda is deeply rooted in classical literature, providing a rich foundation for this research.Sushruta Samhita (2000 B.C. – 800 A.D.) describes the anatomical basis for speech, mentioning two Dhamanis (arteries/channels) for Bhashana (speaking) and two for Ghoshana (producing sound) [11]. It also lists conditions like Gadgada (stammering), Muka (dumbness), and Minmin (unclear speech) as symptoms of Kaphavrita Vata (Vata obstructed by Kapha) affecting the Shabdhavaha Dhamani [12].Charaka Samhita (2000 B.C. – 800 A.D.) elaborates on the pathophysiology, mentioning Vakgraha (speech arrest) in the context of Samanavrita Udana Vata and recommending Nasya (nasal medication) for its management [13, 14]. It also lists Vaksanga (speech obstruction) among the 80 types of Vata disorders, reinforcing the central role of Vata in speech pathology [15]. The text also notes Kalyanaka Ghrita's phalashruti (benefits) for speech [16].Ashtanga Hridaya contributes to the anatomical understanding by stating that four Siras (vessels) are responsible for Vachana (speech) [17].Kashyapa Samhita offers the most comprehensive pediatric perspective. Acharya Kashyapa's unique contribution is his explanation of the Vak Indriya (organ of speech) having two functional parts: one for Vachana (production) and one for Grahana (perception), highlighting that speech is dependent on auditory processing [18]. This explains why a congenitally deaf child (Shrotra as Vakmoola) will be Mooka. He also provides developmental milestones for speech and, most importantly, indicates the use of Samvardhana Ghrita for speech problems, particularly in the context of Phakka Roga, where Mookatwa is a key symptom [7, 19].The fundamentals of Vakpravrutti are governed by Vata, especially Udana Vata. Its seat is the Uras (chest), and its functions include Vak Pravartana (initiation of speech), Prayatna (effort), Bala (strength), and Smriti (memory) [20]. The importance of Swara (voice) in diagnosis is emphasized by Kashyapa, who states that Sara (essence/quality) can be understood by Swara [8].

Research gaps

A primary gap lies in the absence of validated anatomical correlations. While Sushruta Samhita and Ashtanga Hridaya describe specific Dhamanis and Siras dedicated to speech production, no modern

research has systematically mapped these ancient channels to identifiable neuroanatomical structures such as the cranial nerves, cortical speech centers, or vascular supply. The distinction between channels for Bhashana (speaking) and Ghoshana (sound production) remains a theoretical construct without empirical verification through contemporary imaging or anatomical studies.

Mechanistic Subtyping of Speech Disorders

The classical texts present distinct pathophysiological mechanisms—Kaphavrita Vata, Samanavrita Udana Vata, and primary Udana Vata vitiation—yet no clinical research has differentiated speech disorders based on these subtypes. Consequently, treatment selection between Nasya, Kalyanaka Ghrita, and Samvardhana Ghrita lacks evidence-based protocols, remaining reliant on traditional wisdom rather than validated clinical algorithms.

Pediatric Speech Development

Although Kashyapa Samhita offers unique developmental milestones and establishes the critical Shrotra as Vakmoola principle linking hearing to speech, these concepts remain unintegrated with modern pediatric audiology and speech-language pathology. No studies have validated these classical milestones against contemporary developmental standards, nor have they explored the Vak-Shrotra axis in conditions such as auditory processing disorder or childhood apraxia of speech.

Pharmacological and Diagnostic Gaps

The therapeutic potential of Samvardhana Ghrita and Kalyanaka Ghrita for speech disorders remains unevaluated through rigorous clinical trials. Furthermore, the diagnostic use of Swara (voice) as a biomarker for Sara (essence) has not been correlated with objective acoustic analysis, preventing the development of standardized diagnostic tools that bridge classical and modern assessment methodologies. Addressing these gaps would significantly advance integrative approaches to speech disorders.

Research Methodology

This study was designed as a randomized, comparative clinical trial. The protocol was prospectively registered (CTRI/2024/12/078556) and received approval from the Institutional Ethics Committee prior to commencement.

Study Design and Participants:

A randomized comparative clinical trial was conducted on a total of 100 children (n=100) aged 2 to 10 years, diagnosed with speech delay based on predefined diagnostic criteria. Participants were enrolled from the OPD/IPD of the study centers and randomly allocated into two groups of 50 each.

Group A (Trial Group): Received Vakshuddhikara Choorna with Samvardhana Ghrita as an Anupana.

Group B (Control Group): Received Vakshuddhikara Choorna with Honey.

The dose of Vakshuddhikara Choorna was 0.5g BD for children aged 2-5 years and 1g BD for those aged 6-10 years. Interventions were administered for 60 days.

4.2. Assessment Criteria:

Assessment was conducted at baseline (Day 0), Day 30, Day 60, and follow-up on Day 90 using eight subjective parameters:

- Expressive Vocabulary at word level
- Speech Intelligibility of expressive word
- Expressive vocabulary of new words
- Sensitivity to loudness
- Verbal and Nonverbal response to expressive words
- Receptive and expressive language
- Stimulus of excitements and happiness
- Response to request or commands

4.3. Statistical Analysis:

Baseline demographic and clinical characteristics were analyzed using Chi-square tests to confirm group homogeneity. For intergroup comparisons of subjective parameters, the Mann-Whitney U test was used. For intragroup comparisons (changes over time), the Wilcoxon signed-rank test was applied. A p-value < 0.05 was considered statistically significant.

Table 1: Baseline Demographic Comparison of Groups

Demographics	Category	Group A (n=50)	Group B (n=50)	χ^2 Value	Pvalue
Age	2–3 yrs	11 (22.0 %)	12 (24.0 %)	1.8110	0.7700
	4–5 yrs	13 (26.0 %)	13 (26.0 %)		
Gender	Male	29 (58.0 %)	30 (60.0 %)	0.0410	0.8390
	Female	21 (42.0 %)	20 (40.0 %)		

Demographics	Category	Group A (n=50)	Group B (n=50)	χ^2 Value	Pvalue
Habitat	Urban	48 (96.0 %)	45 (90.0 %)	1.3820	0.2400
	Rural	2 (4.0%)	5 (10.0 %)		

(The table shows no significant differences between groups, indicating they were comparable at baseline.)

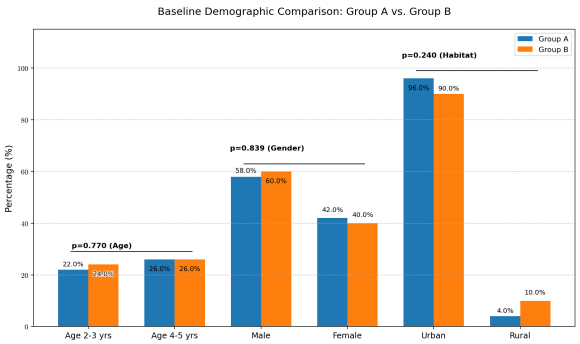

Figure-1 Demographic Comparison Group A Vs Group B

Table 2: Comparison of Speech Intelligibility (Mean Score)

Time Point	Group A (Mean)	Group B (Mean)	% Effect (Group A)	% Effect (Group B)
Before Treatment (BT)	1.4	1.5	–	–
Day 30	1.9	2.0	41.2%	30.3%
Day 60	2.4	2.5	79.4%	63.2%
Day 90	2.8	2.8	105.9%	82.9%

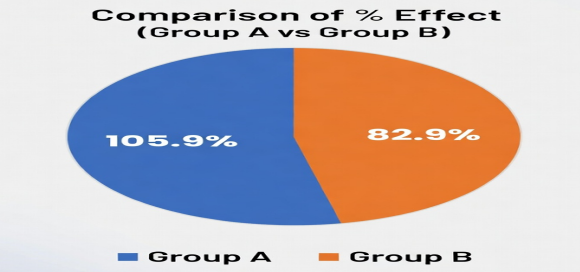

Figure-2-Speech Intelligent at Day 90

$p < 0.05$ (Wilcoxon Signed Rank Test)

Table 3: Comparison of Expressive Vocabulary of New Words (Mean Score)

Time Point	Group A (Mean)	Group B (Mean)	% Effect (Group A)	% Effect (Group B)
Before Treatment (BT)	2.0	2.0	–	–
Day 30	2.7	2.5	35.0%	24.0%
Day 60	3.2	3.0	60.0%	51.0%
Day 90	3.6	3.4	80.0%	72.0%

$p < 0.05$ (Wilcoxon Signed Rank Test)

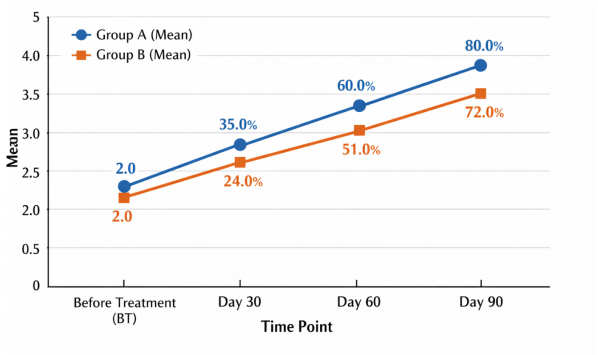

Figure -3-Expressive Vocabulary of New words

A significant intergroup difference was observed in the parameter "Stimulus of excitement and Happiness" at day 30. The Mann-Whitney U test for the change from baseline showed a p-value of 0.0329, with a moderate effect size, favoring Group A.

Results

The present study enrolled 100 children with speech delay, randomized into Group A (Vakshuddhikara Choorna with Samvardhana Ghrita, n=50) and Group B (Vakshuddhikara Choorna with Honey, n=50). Baseline demographic characteristics showed no significant differences between groups, confirming homogeneity ($p>0.05$ for age, gender, and habitat).Both groups demonstrated statistically significant improvement across all eight subjective parameters from baseline to Day 60 and sustained improvement at follow-up (Day 90), with $p<0.05$ on Wilcoxon signed-rank test. However, Group A consistently showed superior therapeutic outcomes compared to Group B, Speech Intelligibility, Group A achieved a 105.9% improvement at Day 90 compared to 82.9% in Group B. In Expressive Vocabulary of New Words, Group A demonstrated 80.0% improvement versus 72.0% in Group B. Other parameters including Expressive Vocabulary at word level, Sensitivity to Loudness, Verbal and Nonverbal responses, Receptive and Expressive language, and Response to requests showed greater improvement in Group A throughout the treatment period. A

significant intergroup difference was observed in the parameter "Stimulus of Excitement and Happiness" at Day 30, with the Mann-Whitney U test yielding a p-value of 0.0329, favoring Group A. This indicates that the add-on therapy accelerated social-emotional responsiveness.No adverse drug reactions were reported in either group. Vital signs and systemic examinations remained within normal limits throughout the study period, confirming the safety and tolerability of both interventions.

Discussion

The results of this study demonstrate the significant therapeutic potential of combining Samvardhana Ghrita with Vakshuddhikara Choorna for managing speech delay in children. Both groups showed significant improvement, confirming the efficacy of Vakshuddhikara Choorna as a primary treatment. However, the trial group consistently exhibited a superior and more rapid therapeutic response, providing strong evidence for the "add-on" effect of Samvardhana Ghrita. The enhanced outcomes in Group A, particularly for Speech Intelligibility (105.9% vs. 82.9%) and Expressive Vocabulary of New Words (80.0% vs. 72.0%), suggest a synergistic action. Vakshuddhikara Choorna, with ingredients like Vacha and Yashtimadhu, likely acts by clearing the Shabdhavaha Srotas (channels of sound) and improving neural communication [9]. Samvardhana Ghrita, a nourishing and rejuvenating formulation, provides a complementary effect. Its ingredients like Bala and Atibala are known for their Balya (strengthening) properties, which could enhance the muscular control required for articulation [10]. The Ghrita base itself is a potent Anupana that enhances the absorption and bioavailability of the active principles of Vakshuddhikara Choorna, thereby amplifying its therapeutic effect. Furthermore, the improvement in vocabulary acquisition aligns with the classical understanding of Udana Vata, which governs memory (Smriti) and effort (Prayatna) [20]. A particularly noteworthy finding was the significant intergroup difference in "Stimulus of excitement and Happiness" at day 30. This parameter, a measure of social and emotional reciprocity, showed a more rapid improvement in Group A. This suggests that the combined therapy may act on a deeper level, potentially improving cognitive engagement and emotional processing, which are crucial foundations for effective communication.The safety profile of both interventions was excellent, with no adverse drug reactions reported. Vital signs and systemic examinations remained within normal limits, confirming the safety of these traditional formulations in the pediatric population.These findings extend previous research. The positive effect of Vakshuddhikara Choorna corroborates the work of Sharashchandra R. [9]. The enhanced outcome in Group A aligns with the findings of Meena M.K., who reported that therapy protocols including Samvardhana Ghrita yielded better results in cerebral palsy patients [10]. This study successfully translates those findings to the broader context of primary speech delay, validating the synergistic potential of this combination.

Conclusion

This randomized comparative clinical study provides compelling evidence that the combination of Samvardhana Ghrita with Vakshuddhikara Choorna is a more effective treatment strategy for speech delay in children compared to Vakshuddhikara Choorna alone. The add-on therapy resulted in superior outcomes, particularly in enhancing speech intelligibility, accelerating the acquisition of new vocabulary, and improving social responsiveness. Samvardhana Ghrita acts as a potent synergist, likely through mechanisms of enhancing drug absorption, strengthening the neuromuscular apparatus of speech, and supporting cognitive functions. The intervention was found to be safe and well-tolerated. This study offers a validated, cost-effective, and holistic Ayurvedic approach to managing a complex pediatric condition, providing clinicians with a promising therapeutic protocol.

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