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Research Article

Ashvagandhadi Lehya

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A Randomized Comparative Clinical Study to Evaluate the effect of Grahanibeelu Leha (Leucas biflora [Vahl] R.Br.) and Ashvagandhadi Lehya in Karshya w.s.r. to Underweight in children

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Undernutrition is a growing concern, particularly in early childhood, significantly contributing to the morbidity and mortality of children, as countries navigate the challenges of economic growth, food insecurity, and changing dietary patterns. From an Ayurvedic perspective, under the umbrella of Kuposhanajanya Vyadhis (Under nutritional diseases), Underweight can be considered under Karshya (Underweight) which refers to a state of emaciation due to inadequate nourishment, which can be managed with nourishing therapies and formulations aimed at enhancing body tissue formation and strength. According to NFHS-4, 35.7% of children under five in India were underweight and comparing to recent data from NFHS-5 (2019-2021) indicate some progress but the problem remains severe in many regions. Hence it is necessary to address Karshya. The trial was proposed to study the comparative effect of Grahanibeelu Leha and Ashvagandhadi Lehya on specific parameters of Karshya w.s.r. to Underweight in children.

Materials and Methods: 1. Children of age group 1-5 years of either gender, fulfilling the diagnostic criteria of Karshya (Underweight), with consent from the parents were selected from Kaumarabhritya OPD of Sri Dharmasthala Manjunatheshwara Ayurveda College, Hospital and Research Centre, Udupi. **2.** Selected subjects will be randomly allocated into 2 groups of 20 patients each. Group A was administered with Grahanibeelu Leha and group B with Ashvagandhadi Lehya with Sukoshna Ksheera as Anupana for both the groups twice daily before food, intervention for 1 month and were assessed before and after treatment with subjective and objective criteria.

Results: The results obtained were statistically analysed and found that, within the group, showed that highly significant improvement in Kshut, Weight and MAC & significant improvement in improving Abhyavaharana Shakti, Baddhavit and Height. However, in the comparative between both groups, Grahanibeelu Leha shows significant result in Abhyavaharana Shakti while other parameters (Kshut, Baddhavit, Weight, Height and MAC) were clinically effective but statistically insignificant.

Conclusion: Both Grahanibeelu Leha and Ashvagandhadi Lehya along with Sukoshna Ksheera are safe and effective in the management of Karshya w.s.r. to underweight in children.

Keywords: Karshya, Grahanibeelu Leha, Ashvagandhadi Lehya

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Introduction

Balyavastha (Childhood) is marked by immature *Dhatus* (Body tissues), making children more vulnerable to diseases, especially undernutrition a common public health issue with multifactorial origins. Underweight is defined as a child's weight being less than -2 standard deviations for their age on WHO growth charts, without symptoms of Kwashiorkor or marasmus.**[1]**

According to NFHS-5 (2019-21), 32.1% of Indian children under 5 are underweight, with 27.3% in urban areas and 33.8% in rural areas. The under-5 mortality is more among severely malnourished children.**[2]**

Karshya, primarily caused by *Dhatukshaya* (Depletion of body tissue), is classified as an *Apatarpanajanya Vyadhi* (Catabolism)**[3]** and symptoms of *Karshya* can be corelated to underweight.

Ayurvedic principles like *Deepana* (Enhancing digestive fire), *Pachana* (Promoting digestion) and *Vatanulomana* (Normalizing the movement of *Vata Dosha*) restore metabolism to address this condition. Traditional medicines are integrative part of health care system confined to particular region.

The trial drug selected here was traditional remedy from Udupi locality, *Grahanibeelu Leha*, used for gastrointestinal disorders since ages. The standard comparator, *Ashvagandhadi Lehya*, known for its *Brumhana* (Nourishing) effects, are both designed to correct *Agni* (Digestive fire) and to regulate the metabolism.

These formulations enhance nutritional status in underweight children, offering a holistic approach that integrates traditional wisdom with modern healthcare to combat undernutrition.

Objectives

1. To evaluate the effect of *Grahanibeelu Leha* (*Leucas biflora [Vahl] R.Br.)* in the management of *Karshya* (Underweight).
2. To evaluate the effect of *Ashvagandhadi Lehya* in the management of *Karshya* (Underweight).
3. To evaluate the comparative effect of *Grahanibeelu Leha* (*Leucas biflora [Vahl] R.Br.*) and *Ashvagandhadi Lehya* in the management of *Karshya* (Underweight).

Materials and Methods

Source of data: The study was approved by Institutional Ethics Committee (Ref: SDMCAU/ACA-49/ECH 33/2022-23). Children fulfilling diagnostic criteria for *Karshya* (Underweight) were enrolled for this clinical study, sele. from OPD & IPD of SDM college of Ayurveda, Hospital and Research Centre, Kuthpady, Udupi.

Diagnostic Criteria: Children with weight for age between 60-80% with symptoms of less *Kshut* (Reduced state of hunger), *Abhyavaharana Shakti* (Capacity to eat) and *Baddhavit* (Irregular bowel habits).

Inclusion Criteria

The children of either gender between the ages of 1 to 5 years, having 2 or more above said symptoms of *Karshya* with weight of child less than expected as per the age i.e., Grade 1 (71-80%) and Grade 2 (61-70%) according to IAP classification of Malnutrition are included.

Exclusion Criteria

Children with Grade 3 (51-60%) and Grade 4 (<50%) malnutrition, having other acute & chronic systemic illness or requiring emergency management**,** inborn error of metabolism, congenital abnormalities, developmental disorders like cerebral palsy, intellectual disability and neurobehavioral disorders like ADHD, autism etc are excluded.

Intervention

Dosage form: *Avaleha*

Dosage: Dose is fixed by considering the age & adult dose, by applying Young's formula.

- For 1-2 year child: 2.5 grams twice daily.
- For 3-5 year child: 5grams twice daily.

Route of administration: Orally, twice daily, before food

- Group A - *Grahanibeelu Leha*
- Group B - *Ashvagandhadhi Lehya*

***Anupana*:** *Sukoshna Ksheera* (Warm milk)

Duration of Study:

- **Duration of treatment:** 1 Month.
- **Clinical assessment:** before treatment (0th day), and after treatment (30thday).

- **Follow up period:**
  - During treatment - 15th day & 30th
  - After treatment - 45th day & 60th
- **Total duration of study:** 2 months.

The written informed consent of the parent/guardian is invariably taken prior to his/her child's inclusion in the study.

Assessment Criteria

A detailed case sheet Performa will be prepared and filled with proper history taking, personal history, physical examination and assessment will be done based on diagnostic criteria.

Subjective criteria

- *Kshut* (State of hunger)
- *Abhyavarana Shakt*i (Capacity to eat)
- *Baddhavit* (Constipation / Irregular bowel habit)

Assessment of clinical features of *Karshya* depending on the Assessment scale are graded as Nil – G0, Mild – G1, Moderate – G2, Severe – G3.

Table 1: Shows the Assessment Parameters.

Kshut (State of hunger)
G0 - Child himself ask food & takes adequately
G1 - Child himself ask food but doesn't take adequately
G2 - Child doesn't ask but takes food considerably by request
G3 - Child doesn't take food considerably even by force
Abyavaharanasakti (Capacity to eat)
G0 - Taking food in normal quantity thrice in a day
G1 - Taking food in less quantity twice in a day
G2 - Taking food in less quantity once in a day
G3 - Not at all taking food
Baddhavit (Constipation / Irregular bowel habits)
G0 - Once in a day
G1 - Once in 2 days
G2 - Once in 3 days
G3 - Once in a week

Objective Criteria

Anthropometric parameters: Weight (in Kg), Height (in cm) and Mid arm circumference (in cm).

Statistical methods: Statistical analysis was carried out using the Statistical Package for Social Science (SPSS) VER.20.

Observations

Table 2: Observation Parameters

Observation Parameters	% of Distribution in 40 subjects	
Age	1-2 year	40.0
	2-3 year	17.5
	3-4 year	15.0
	4-5 year	27.5
Gender	Male	55.0
	Female	45.0
Socioeconomic status	Upper middle class	42.5
	Lower middle class	47.5
	Upper lower	10.0
Locality	Rural	80.0
	Urban	20.0
Chief complaints	Weight less for Age	100
	Reduced state of Hunger	100
	Refusal for food intake	75
	Irregular bowel habits	47.5
Birth weight	SGA	15.0
	AGA	80.0
	LGA	5.0
H/O Low Birth Weight	17.5	
Duration of breastfeeding	Less than 6 months	15.0
	Up to 6 months	55.0
	More than 6 months	30.0
Number of Servings per day	2 to 3	47.5
	3 to 4	35.0
	4 to 5	17.5
H/O Deworming	Done	65.0
	Not done	35.0
Diet (Vegetarian / Mixed)	50 % each	

Results

Effect of treatment on Subjective Parameters

Within the group: Wilcoxon Signed-Rank Test

Table 3: Effect of *Kshut, Abhyavaharana Shakti* and *Baddhavit* within the groups

Parameter	Negative Ranks			Positive Ranks			Ties	Total	Z value	P value	Inference
	N	MR	SR	N	MR	SR					
Grahanibeelu Leha (Kshut)											
BT-AT	20	8	210	0	0.0	0.0	0	20	-3.53	0.0001	HS
BT-FU	20	8	190	0	0.0	0.0	0	20	-3.53	0.00	HS

Ashvagandhadi Lehya (Kshut)											
BT-AT	20	8	210	0	0.0	0.0	0	20	-3.50	0.0001	HS
BT-FU	20	8	171	0	0.0	0.0	0	20	-3.58	0.0001	HS
Grahanibeelu Leha (Abhyavaharana shakti)											
BT-AT	10	5.5	153	0	0.00	0.0	5	20	-3.16	0.0002	HS
BT-FU	10	5.5	78	0	0.00	0.0	5	20	-3.16	0.0031	S
Ashvagandhadi Lehya (Abhyavaharana shakti)											
BT-AT	3	2	190	0	0.00	0.0	12	20	-1.7	0.0001	S
BT-FU	3	2	120	0	0.00	0.0	12	20	-1.7	0.0001	S
Grahanibeelu Leha (Baddhavit)											
BT-AT	4	2.5	55	0	0.0	0.0	11	20	-2.0	0.04	S
BT-FU	4	2.5	55	0	0.0	0.0	1	20	-2.0	0.04	S
Ashvagandhadi Lehya (Baddhavit)											
BT-AT	7	4.5	66	0	0.0	0.0	7	20	-2.1	0.034	S
BT-FU	7	4	45	0	0.0	0.0	8	20	-2.6	0.008	S

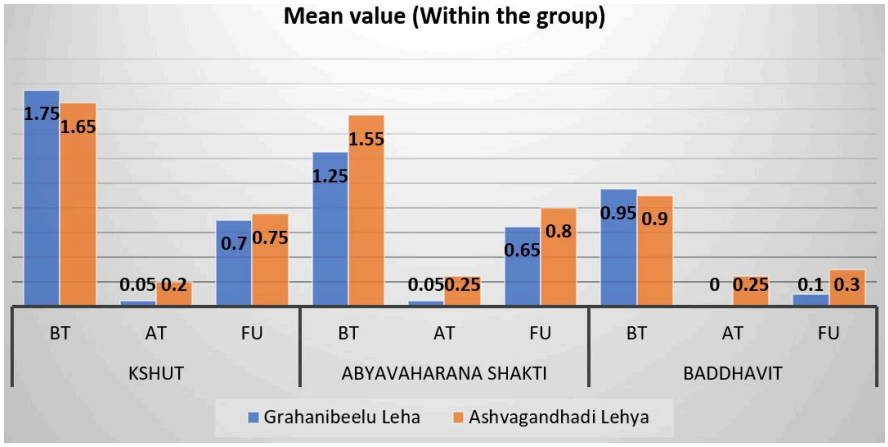

Figure 1: Mean values of *Kshut, Abhyavaharana Shakti* and *Baddhavit* within the groups

Between the group: Mann Whitney Test

Table 4: The Effect of *Kshut, Abhyavaharana Shakti* and *Baddhavit* Between the groups

Parameters	N	Group- A (N)	Group- B (N)	Mean		Sum rank		U value	ZValue	Pvalue	Interpretation
Kshut											
BT-AT	40	20	20	0.05	0.2	380	440	170	-1.28	0.16	NS
BT-FU	40	20	20	0.7	0.75	206	259	86	-1.28	0.2	NS
Abhyavaharana Shakti											
BT-AT	40	20	20	12	19	180	285	60	-2.5	0.01	S
BT-FU	40	20	20	15	15	232.5	232.5	112	0.00	1	NS
Baddhavit											
BT-AT	40	20	20	16.6	17	249	255	95	-0.8	0.411	NS
BT-FU	40	20	20	14.3	14	215	210	90	-1.1	0.264	NS

Effect of treatment on Objective Parameters:

Within the group: Paired t test

Table 5: The Effect of Weight, Height and MAC Within the group

Mean score		N	SD	S.E.M	Mean difference	%	T	PValue	Interpretation
Grahanibeelu Leha (Weight)									
BT	AT	20	0.26	0.67	-0.48	3.9	7.08	0.00	HS
9.72	10.45								
BT	FU	20	0.29	0.77	-0.75	5.9	9.73	0.00	HS
12.1	10.45								

Mean score		N	SD	S.E.M	Mean difference	%	T	PValue	Interpretation
Ashvagandhadi Lehya (Weight)									
BT	AT	20	-0.43	0.47	-0.43	3.3	9.1	0.00	HS
13.0	13.4								
BT	FU	20	-0.74	0.56	-0.74	5.6	13.1	0.00	HS
13.0	13.7								
Grahanibeelu Leha (Height)									
BT	AT	20	0.271	0.070	-0.17	0.17	2.4	0.027	S
95.6	95.7								
BT	FU	20	0.275	0.071	-0.20	2.0	2.8	0.014	S
95.6	95.8								
Ashvagandhadi Lehya (Height)									
BT	AT	20	0.10	0.028	0.07	0.07	2.5	0.022	S
99.3	99.4								
BT	FU	20	0.27	0.94	0.18	0.18	2.5	0.022	S
99.3	99.4								
Grahanibeelu Leha (MAC)									
BT	AT	20	0.507	0.83	0.086	0.52	4.02	0.001	HS
15.10	15.18								
BT	FU	20	0.501	0.129	0.180	1.0	4.32	0.001	HS
15.1	15.28								
Ashvagandhadi Lehya (MAC)									
BT	AT	20	0.94	0.243	0.12	0.77	4.9	0.00	HS
15.4	15.5								
BT	FU	20	0.96	0.248	0.17	1.1	6.9	0.00	HS
15.4	15.6								

Between the group: Unpaired t- Test

Table 6: The Comparative Effect of Weight, Height and MAC Between the group (Group-A *Grahanibeelu Leha* and Group-B *Ashvagandhadhi Lehya*)

	Group	N	M.D	S.E.M	T	P	Interpretation
Weight							
BT-AT	Group-A	20	0.48	0.06	0.56	0.57	NS
	Group-B	20	0.43	0.04			
BT-FU	Group-A	20	0.82	0.09	0.66	0.51	NS
	Group-B	20	0.74	0.05			
Height							
BT-AT	Group-A	20	0.17	0.070	1.3	0.19	NS
	Group-B	20	0.07	0.028			
BT-FU	Group-A	20	0.20	0.071	1.4	0.20	NS
	Group-B	20	0.18	0.069			
MAC							
BT-AT	Group-A	20	0.086	0.024	1.02	0.319	NS
	Group-B	20	0.042	0.021			
BT-FU	Group-A	20	0.093	0.033	1.03	0.321	NS
	Group-B	20	0.053	0.026			

Effect of treatment

- **Within the group:** Statistically, both groups showed highly significant improvements in *Kshut*, weight, and MAC, with significant improvements seen in *Baddhavit* and height. In *Abhyavaharana Shakti*, Group A showed highly significant improvement, while Group B showed significant improvement.
- **Between the group:** In *Abhyavaharana Shakti*, Group A showed significant improvement, but both groups showed insignificant results for all other parameters. However, clinically, both groups were effective.

Discussion

Nutrition and growth go hand in hand, forming the foundation of a child's healthy development. Yet, undernourishment continues to be a critical challenge in many developing nations, hindering the potential of countless young lives. In India the prevalence rate is 13.7% as per the Global Hunger Index 2024,**[4]** despite growing concerns and various government programs aimed at reducing its prevalence. From the breastfeeding stage to childhood, nutritional disorders take many forms, with Ayurveda identifying conditions like *Parigarbhika, Balashosha,* and *Karshya*. Ayurveda is the holistic science, aiming to eliminate diseases at their root by addressing the underlying causes. Through therapies such as *Deepana* (Enhancing digestive fire), *Pachana* (Promoting digestion), *Balya* (Strengthening), and *Brimhana* (Nourishment), Ayurveda provides a comprehensive pathway to restore and sustain health.

Discussion on formulation:

Documenting and studying ethno-medical knowledge holds immense potential to enhance modern therapeutic approaches. In view of this clinical trial drug is selected from folk practice of Udupi Locality. i.e., *Grahanibeelu Leha* which helps to improve *Agni* and promote weight gain in children.**[5]** As the name itself suggest, *Grahanibeelu* helpful in treating *Grahani vikara*. The activities such as hepatoprotective, immunomodulatory, anti-microbial etc. helps to maintain the digestive system in good condition. Hence, effective in the management of *Karshya*.

Ashvagandhadi Lehya is a well-known formulation, praised for its *Balya* (Strengthening) and *Rasayana* (Rejuvenating) properties, effective in managing *Karshya* and suitable for all age groups. Alkaloids in *Withania somnifera* have been reported that promote browning of adipose tissue, improve energy expenditure by adaptive thermogenesis.**[6]**

Discussion on Observation

Undernutrition is more prevalent in the below 5-year age group. Among 40 subjects, majority belongs to 1-2 age group. At this age, the introduction of family food makes mothers more attentive to their child's eating habits, often prompting them to seek medical advice.

No significant difference is seen in how it affects individuals based on gender. Economic barriers that limit the ability to purchase nutritious food for children affect their nutritional status. All 40 subjects reported concerns of being underweight for their age, a worry observed by mothers who sought help due to insufficient weight gain and reduced appetite in their children.

These issues may be attributed to factors such as improper breastfeeding, delayed introduction of weaning foods, or a preference for bakery products, which are often low in calories and essential nutrients, leading to inadequate weight gain for their age. Children presented with complaints of food refusal, a common issue as young children often exhibit neophobia and are perceived as picky eaters by their parents. They tend to prefer self-feeding and become more selective in their food choices. When pressured or forced to eat, children may resist in order to assert their autonomy.**[7]** Unhealthy eating habits can disrupt regular bowel patterns and should be addressed to prevent chronic constipation.

The prevalence of underweight is higher in Low birth weight (LBW) and Small for Gestational Age (SGA) babies. Breast milk is essential for infants, and insufficient intake affects weight gain. Delays in weaning and limited servings per day impact healthy weight gain, as breast milk alone is insufficient after 6 months. There was an equal distribution of vegetarian and mixed diets, in both groups. Since most deworming campaigns target school-aged children, 35% were not received any deworming medication.

Discussion on Results:

Subjective parameters

Kshut: Both groups showed highly significant improvement in *Kshut* before & after treatment and before & follow-up, with p-values of 0.0001 and 0.00, respectively. For *Rasapradoshaja vikara, Tikta Rasa* aids *Pachana* and clears the *Srotas*. *Grahanibeelu Leha* is primarily *Tikta-Katu* with mild *Madhura Rasa* and *Snigdha Guna*, while *Asvagandhadi Lehya,* also predominantly *Madhura*, enhances appetite through its *Deepana, Pachana, Dhatuvardhana* (Nourishment promoting tissue growth), *Rasayana* (Rejuvenation), and *Balya* properties improves *Kshut*.

***Abhyavaharana Shakti*:** Compared between groups, *Grahanibeelu Leha* showed a significant increase in *Abhyavaharana Shakti* (p-value 0.01) before and after treatment. *Rochana* property is enhanced by own action of *Tikta Rasa*. So, there might be difference in both the group before treatment and at follow up. Both groups exhibit *Krimigna* (Antimicrobial and anthelmintic) properties, which may support gut health and improve food intake capacity.

***Baddhavit*:** Improper bowel patterns are often considered a symptom rather than a disease in many conditions. Both formulations support digestive health through *Anulomana* action, with *Grahanibeelu Leha* containing *Draksha* to balance *Vata*, and *Ashvagandhadi Lehya* featuring *Madhusunhi* for its purgative effects.

Objective parameters

Weight: The mean difference before & after treatment and before & follow-up was 0.48 and 0.75 for Group A, and 0.43 and 0.74 for Group B. Group A's higher sugar content suggests rich caloric value which helps to regulate metabolism and nutrient absorption.**[8]** Similarly, the *Brumhana* and *Rasayana* effects of Group B also support healthy weight gain.

Height: Height is primarily determined by genetics, but nutrition significantly influences growth and hormone regulation. In this study, height changes of 0.3 cm to 1 cm were observed, indicating the added benefit of Leha for height growth.

MAC: MAC is age-independent, showing minimal changes during the intervention, but remaining static or decreasing during the follow-up period.

Overview: *Agni* is revitalized by *Deepana* and *Pachana* herbs, which have *Tikta, Katu Rasa,* and *Laghu, Ushna Guna,* promoting digestion, metabolism, and nutrient transformation. These properties clear blockages in the minute *Srotas,* restore nutrient flow, and nourish the *Dhatus,* contributing to healthy weight gain and improving other anthropometric values. *Balya* and *Rasayana* herbs, rich in *Madhura Rasa* with *Guru, Snigdha* qualities rebuild strength and promote weight gain and boosting the immunity. Both formulations, possessing these qualities, are highly effective in treating *Karshya*. The clinical study revealed improvements in appetite, food intake, Regular bowel patterns by relieving constipation, and anthropometric parameters, with no adverse effects during the intervention and follow-up periods. This contributed to the relief of symptoms of *Karshya*. Both *Grahanibeelu Leha* and *Ashvagandhadi Lehya* formulations are equally effective, due to their *Deepana, Pachana, Srotoshodhana* and *Vatanulomana* properties successful in breaking the *Samprapthi.*

Conclusion

Statistically both the groups showed highly significant results in improvement of *Kshut,* Weight and MAC and significant improvement seen in *Baddhavit* and Height. *Grahanibeelu Leha* showed highly significant result in *Abhyavaharana Shakti* where as *Ashvagandhadi Lehya* showed significant improvement in the same parameter. The present study, Clinically & statistically discloses both *Grahanibeelu Leha* and *Ashvagandhadi Lehya* are equally effective in the management of *Karshya*. Both formulations were well-tolerated by the subjects, with no adverse reactions reported throughout the study's duration.

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