



## A Clinical Trial to Evaluate the Combined Effect of Kulattha Yusha with Vidanga Churna in the Management of Hypothyroidism

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Hypothyroidism is one of the most common thyroid disorders. An underactive thyroid gland characterizes it. The prevalence of hypothyroidism in India is around 11%, and Females suffer more than males, with a ratio of 6:1. The prevalence of clinical Hypothyroidism is about 4%. WHO initiated the project to fight thyroid hypofunction. From an Ayurvedic perspective, Hypothyroidism is characterized by Agnimandya (diminution of Agni), affecting both Jataragni (Digestive power) and Dhatwagni (metabolic factors located in Dhatu). It involves increased Kapha and Vata Doshas and decreased Pitta Dosha, often exacerbated by an unhealthy diet, sedentary lifestyle, and chronic stress. Treatment should focus on Agnideepana (enhancing metabolic fire), Kaphavatahara, and Pittakara principles. This clinical trial investigates the combined effect of Kulattha Yusha (Horse gram soup) and Vidanga Churna, which are recommended for their supportive properties used in managing Hypothyroidism. With this approach, the current study was designed to evaluate the combined effect of Kulattha Yusha (Horse gram soup) and Vidanga Churna in the management of hypothyroidism.

**Materials and Methods:** The data were collected on the 0th day, 61st day, and 90th day after completing the Kulattha Yusha (Horse gram soup) with Vidanga Churna treatment.

**Results:** The results indicate that the combined use of Kulattha Yusha (Horse gram soup) and Vidanga Churna showed clinically and statistically highly significant results in reducing hypothyroidism symptoms such as obesity, multiple joint pain and stiffness, heaviness of the body, loss of appetite, and the Zuwelski Total Scale Score for hypothyroidism, as well as a reduction in TSH levels, with a significant p-value of 0.000

**Discussion:** Kulattha Yusha, and Vidanga Churna known for its properties of Ushna, Tikshna, Kaphavatahara, Medhaghna, Agnideepana, and Vibandhahara, serves as an effective remedy for supporting thyroid function and restoring balance of Doshas.

**Keywords:** Hypothyroidism, Kulattha Yusha, Pathya, Vidanga Churna, Zuwelski total score

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## Introduction

Hypothyroidism is one of the most prevalent endocrine disorders worldwide. It is characterized by a hypo-metabolic clinical state, resulting from inadequate production of thyroid hormone. This condition mainly affects Basal metabolic rate and physical, mental growth.

It is associated with symptoms like poor appetite, weakness or tiredness, feelings of cold, poor memory, constipation, and weight gain. According to an epidemiological study conducted in India, 40 million people suffer from thyroid disorders. The prevalence of hypothyroidism in India is around 11%, and Females suffer more than males with a ratio of 6:1. The prevalence of Hypothyroidism is about 4%. Subclinical hypothyroidism is 6 to 8% in women and 3% in men.[1]

The thyroid hormone regulates all metabolic activities in the body. Thyroxine can be composed as *Kayaagni Amsa (metabolic factors of the body)* [2], nothing but a hypo-functional state of *Agni* (digestive fire). It can be compared to *Agnimandhya (diminution of agni)*, involving both *Jataragni (digestive fire)* and *Dhatvagni (metabolic factors located in dhatu)*.

When analyzing the signs and symptoms of hypothyroidism from an Ayurvedic view, *Agnimandya (diminution of Agni)* due to *Kapha-Vata Vriddhi* and *Pittakshaya* is observed. This is often caused by unhealthy food habits, non-nutritious food, and a sedentary lifestyle.

Hypothyroidism is often caused by improper dietary habits and iodine deficiency, making changes in diet and lifestyle play a significant role in controlling thyroid hormone levels. In *Ayurveda*, much importance is given to *Pathyahara Sevana* (wholesome diet). Proper *Pathyahara Sevana* (wholesome diet) has an important role in managing diseased conditions by regulating the body's metabolic function and balancing the *Tridosha*, which is considered more significant than medicine. This clinical trial aims to bridge this gap by systematically investigating the combined effect of *Kulattha Yusha (Horse gram soup)* and *Vidanga Churna* in patients with hypothyroidism. *Kulattha Yusha (Horse gram soup)* has *Kaphavatahara*, *Medhaghna*, *Agni Deepana (enhancing metabolic fire)*, and *Vibandhahara* properties.

## Aims and Objectives

1. To evaluate the Combined effect of *Kulattha Yusha (Horse gram soup)* and *Vidanga Churna* in the management of Hypothyroidism.
2. Alleviating hypothyroidism-related symptoms and enhancing overall patient well-being

## Materials and Methods

### Source of data

Subjects were diagnosed and selected from the OPD & IPD of Government Ayurvedic Medical Hospital, Mysuru, and Government Hi-Tech Panchakarma Centre, Mysuru.

### Source of the drug

The formulation of *Kulattha Yusha (Horse gram soup)* is mentioned in *Kaiyadeva Nighantu*, *Kashyapa Samhita*. And *Vidanga Churna* mentioned in *Bhavaprakasha Nighantu*, manufactured by a GMP-certified pharmacy, S.N. Pandita and Son's Co Pvt Ltd, Mysuru, was procured for the study.

### Diagnostic criteria

The diagnosis was based on objective and subjective criteria.

1. Objective criteria: Thyroid function test
2. Subjective criteria: Clinical features of Hypothyroidism

### Inclusion criteria

1. Subjects of the age group between 20-50 years fulfilling the diagnostic criteria were selected for the study.
2. Subjects with a TSH value >5.5mIU/L to <25mIU/L not be associated the routed value of T3 and T4.

### Exclusion criteria

1. Subjects with congenital hypothyroidism, chronic history of hypothyroidism, and secondary hypothyroidism
2. Subjects having any of the diagnosed systemic illnesses that interrupt the present intervention.
3. Subjects with toxic goiter, pregnant and lactating women are excluded.
4. Subjects who have undergone any thyroid surgery.
5. Subjects having *Amlapitta*

## Study design

Single-group observational study with pre- and post-study design.

Sample size: The study was conducted on 30 subjects

Sampling techniques: Purposive sampling

Duration of the intervention: 60 days, follow-up period 30 days.

## Intervention

**Table 1: Ingredient of Vidanga Churna[3],[4] and Kulattha Yusha[5],[6]**

Ingredients	Scientific Name	Quantity	Anupana	Time of administration	Dosage
<b>Vidanga</b>	Embelia ribes Burn. F	12gms	Ushna Jala	Pragbhaktha[7] in divided doses (6 gms each) after breakfast and after dinner.	12 gm[8] in an equally divided dose (i.e., 6gms twice/day)
<b>Kulattha Yusha</b>					
<b>Kulattha</b>	Dolichos biflorus Linn	20gms		Morning (empty stomach), once a day. (Subjects were advised to have breakfast if he/she felt hungry).	100ml
<b>Pippali</b>	Piper longum Linn	QS			
<b>Shunti</b>	Zingiber officinale	QS			
<b>Saindava</b>	Rock salt	QS			
<b>Jala</b>	Water	360ml			

**Table 2: Showing properties of Kulattha Yusha and Vidanga Churna**

Ingredients	Rasa	Guna	Virya	Karma
<b>1. Kulattha</b>	Kashaya	Ushna, Tikshna	Ushna	Kapha- Vatanashaka, Kasa, Shwasa, Hikka, Arshahara Medhohara
<b>2. Shunti</b>	Katu	Ruksha, Tikshna, Guru	Ushna	Agnideepana, Kasa, Shawasahara
<b>3. Pippali</b>	Katu	Laghu, Tiksha, Snigdha	Ushna	Deepana, Kaphavatahara, Jwaragna, Rasayana
<b>4. Saindava</b>	Lavana, Madhura	Snigdha, Sukshma, Laghu	Sheeta	Deepana, Pachana, Ruchya, Tridosahara

## Preparation of Vidanga Churna

Vidanga Churna was sourced from the GMP-certified NKCA pharmacy in Mysuru, and a standardization certificate was obtained. The obtained final product in powder form was filled in airtight packets, each of which contained a dose for 30 days.

## Preparation of Kulattha Yusha

The raw drug Kulattha was procured from FISSA-certified packets. The Prakshepaka Dravya powder was prepared at NKCA Pharmacy in Mysuru, with a standardization certificate obtained. The final product was packed in airtight packets, each weighing 5 grams. Kulattha (Horse gram) and Prakshepaka Dravya were packed separately, following hygienic precautions.

## Method of preparation

For preparation, each subject received a packet containing a daily dose of 20 grams of crushed Kulattha (Horse gram) along with the necessary amount of Prakshepaka Dravya. The subjects were instructed to mix the contents with 360 ml of water and boil until the mixture reached a semi-liquid consistency. After boiling, Ghrita Bhargitha Prakshepaka Dravyas, such as Shunti (Zingiber officinale), Pippali Churna (Piper longum), and Saindava Lavana (rock salt), were added.

## Assessment schedule

- Pretest - 0th day
- Post-test - 61st day
- Follow-up - 90th day

## Assessment criteria

**Table 3: Subjective Criteria: ZULEWSKI's clinical score for hypothyroidism[12]**

Based on Symptoms	New score	
	Present	Absent
1. Diminished sweating	1	0
2. Hoarseness	1	0
3. Dry skin	1	0
4. Constipation	1	0
5. Weight increase	1	0
6. Paresthesia	1	0
7. Impairment of hearing	1	0
Physical signs		
1. Coarse skin	1	0
2. Cold skin	1	0
3. Periorbital puffiness	1	0
4. Slow movements	1	0
5. Delayed ankle reflex	1	0

The sum of all symptoms and signs present:

A score of >5 points defines hypothyroidism.

A score of 0-2 points defines the euthyroid.

### Statistical methods

The results were analyzed statistically by using the paired 't' test, chi-square test, repeated measures ANOVA as inferential statistics, and descriptive methods like Mean, Standard deviation, Frequency, and Percentage using SPSS for Windows software.

## Observations and Results

In the present study, it was observed that Hypothyroidism was common in the age group of 31-40 years, most participants were females, 83.3%, and 10 16.7% were males. 60 % were homemakers, and 25% of participants had a history of PCOS. 75% of participants were on a mixed diet, 67%. 7% had *Vishamagni* (*vitiating Agni*), 66.7% of participants had a history of *Diwaswpna* (*day sleep*), and 48.3% of participants with a BMI of 25.0-29.0. 43.8% of participants had irregular menstrual cycles, and 71.7% had pallor. 46.7% of participants had emotional disturbance.

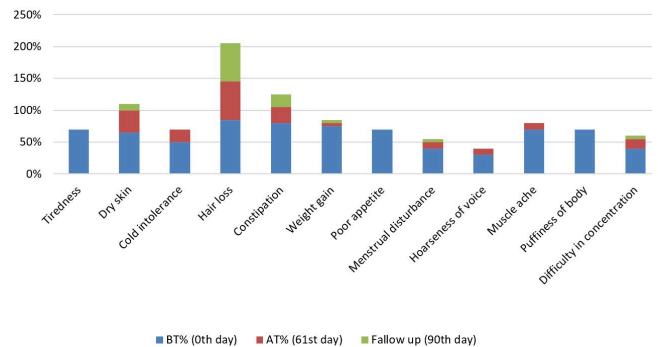
**Table 4: Showing subjective parameters: ZULEWSKI's Scale, Total score before, after treatment, and follow-up**

Score	BT% (0th day)	AT% (61st day)	Follow up (90th day)
Tiredness	70%	0%	0%
Dry skin	65.0%	35.0%	10.0%
Cold intolerance	50.0%	20.0%	0.0%
Hair loss	85.0%	60.0%	60.0%
Constipation	80.0%	25.0%	20.0%
Weight gain	75.0%	5.0%	5.0%
Poor appetite	70.0%	0.0%	0.0%
Menstrual disturbance	40.0%	10.0%	5.0%
Hoarseness of voice	30.0%	10.0%	0.0%
Muscle ache	70.0%	10.0%	0.0%
Puffiness of the body	70.0%	0.0%	0.0%
Difficulty in concentration	40.0%	15.0%	5.0%

**Table 5: Showing overall assessment results**

Improvement	Number of subjects	Percentage %
Marked improvement	17	56.1%
Moderate improvement	9	30.0%
Mild improvement	4	13.2%
No improvement	0	0
Total	30	100%

Overall assessment was done based on the subjective parameters of ZULEWSKI's Scale Total score. After treatment, on the 61st day, 17 (56.1%) subjects had marked improvement, 9 (30.0%) subjects had moderate improvement, and 4 (13.2%) subjects had mild improvement.



**Figure 1: Showing Graphical presentation of ZULEWSKI's Scale, Total score before, after treatment, and follow-up.**

## Discussion

### Discussion on Hypothyroidism

The thyroid gland is one of the most important endocrine glands in the body. Thyroid hormones are essential for normal metabolism, growth, and development. While pinpointing the exact correlation between Hypothyroidism and a specific *Ayurveda* disease condition can be challenging, understanding it becomes clearer when viewed through the principles of *Ayurveda*.

In *Ayurveda*, the functions of the thyroid gland can be correlated with *Agni* (*digestive fire*), particularly in digestion and metabolism. The thyroid hormones influence metabolic processes in nearly all the body cells, mirroring the role of *Agni* (*digestive fire*).

Thus, *Agnivaishamya* (*vitiating of Agni*) can be considered a root cause of thyroid dysfunction, which can be linked to *Mandagni*, specifically *Jatharagni* (*digestive fire*), and *Dhatvagnimandhya*, leading to the formation of *Ama* and subsequent *Rasa Dhatvagnimandhya*.

Factors contributing to *Mandagni* include improper diet and lifestyle, which disturb *Tridosha* (*Vata-Kapha Vriddhi*, and *Pitta Kshaya*). The resulting *Ama* causes *Srotoavarodha* (*obstruction of Srotas*), particularly in *Rasa*, *Rakta*, *Mamsa*, and *Meda Dhatu*. The vitiated *Dosha* and *Dushya* ultimately affect the thyroid gland, leading to Hypothyroidism.

### Discussion on Kulattha Yusha

*Kulattha Yusha*, a dietary formulation from the *Sushruta* and *Kashyapa Samhitas*, is primarily composed of *Kulattha* (Horse gram), *Shunti* (Ginger), *Pippali* (piper longum), and *Saindava* (rock salt). It is recognized for its *Ushna*, *Tikshna*, *Agni Deepana*, and *Ruksha* qualities, which help balance *Vata* and *Kapha* while stimulating *Pitta*. This formulation is used to address respiratory conditions such as *Peenasa* (chronic rhinitis) and *Kasa* (cough), as well as metabolic disorders like *Meha* (diabetes) and *Medo Roga*.

- **Agni Deepana:** Enhances digestive fire, improving nutrient absorption and metabolism.
- **Kapha-Vatahara:** Balances *Kapha* and *Vata* *Doshas*, supporting metabolic health and thyroid function.
- **Medhohara:** Reduces excess fat, assisting in weight management and metabolic rates.
- **Vatanulomana:** Normalizes *Vata*, improving digestion and addressing metabolic disturbances.
- **Sara:** Boosts vitality and energy, counteracting fatigue.
- **Svedakara:** Promotes sweating and detoxification, enhancing overall metabolic health.

### Discussion on Prakshepaka Dravya

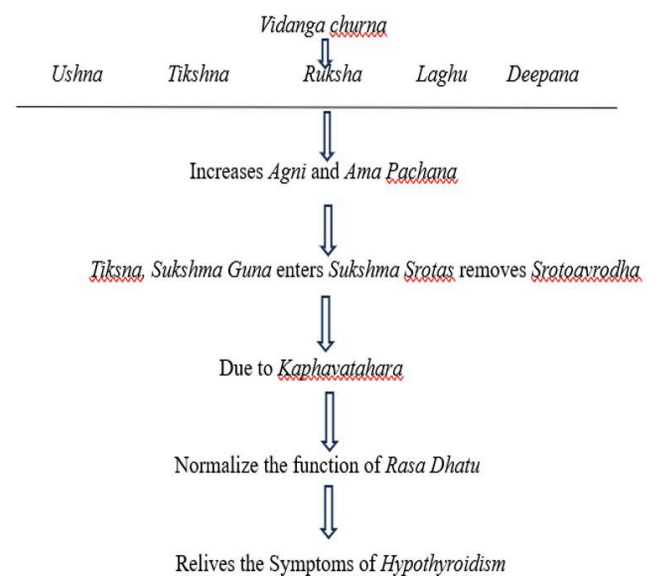
Ayurvedic principles assert that *Samskara* can transform the qualities of food, as expressed in "*Samskaro hi Gunantaraadhanamuchyate*." When processed with *Shunti* (ginger), *Pippali* (piper longum), and *Saindava* (rock salt), *Kulattha Yusha* (horse gram soup) enhances its properties and exhibits qualities such as *Agni Deepan*, *Medohara*, *Kapha-Vatahara*, *Vatanulomana*, *Sara*, and *Svedakara*.

In hypothyroidism, which is characterized by *Agnimandhya* (diminution of *Agni*) and imbalances in *Kapha-Vata* along with *Rasa Dushthi*, *Kulattha Yusha* targets the root cause of the condition - *Agnimandhya* (diminution of *Agni*) - by improving metabolic function. *Saindavana Lavana*, as described in the *Charaka Samhita*, is characterized as *Laghu*, *Snigdha*, and *Teekshana*, and has properties such as *Agni Deepana*, *Pachana*, *Rochana*, *Vrishya*, and *Hridya*.

It is indicated for *Shotahara*, *Vibhandagna*, and is *Tridosham Shamaka*, helping to enhance *Agni* and *Ama Pachana* while removing *Srotoavarodha*. Additionally, it contains minerals and elements like iodine, lithium, magnesium, phosphorus, iron, and zinc. Iodine is crucial for synthesizing the thyroid hormones T3 and T4, as the thyroid gland uses it to incorporate into the amino acid tyrosine for hormone formation.

### Discussion on Vidanga Churna

According to the *Charaka Samhita* (C. Su. 25/40), *Vidanga* is described as *Krimighna*. The *Sushruta Samhita* (Su. S. 25) identifies it as *Krmighna*, *Kusta*, *Pramehara*, and *Kapha-Vatahara*. It is particularly relevant for conditions resulting from *Santarpana Janya Vyadhi* or metabolic disorders, such as hypothyroidism, which involves an under-functioning thyroid gland and is characterized by metabolic imbalance. The action of *Vidanga Churna* is shown in below flow chart below.



**Flow Chart 1: Showing the mode of action of Vidanga Churna**

### Discussion on Subjective Parameters

*Vidanga Choorna* and *Kulattha Yusha* offer significant benefits for addressing various symptoms related to hypothyroidism and *Dosha* imbalances. *Vidanga Churna* enhances *Agni* (digestive fire), supports thyroid function, and helps alleviate tiredness, dry skin, poor appetite, and muscle aches by balancing *Vata* and improving digestion. *Kulattha Yusha* (horse gram soup), with its *Ushna* and *Tikshna* properties,



Aids in reducing cold intolerance, hair loss, weight gain, and puffiness while boosting *Agni* and circulation. Despite using *Vidanga Choorna* and *Kulattha Yusha*, no significant results were observed in addressing hair loss, difficulty in concentration, dry skin, and hoarseness of voice. While these remedies are known for their benefits in improving digestion and balancing *Doshas*, their effectiveness in resolving these specific symptoms was limited in this study. Further investigation may be required to fully assess their impact on these conditions. *Vidanga Churna* has *Agni Deepana* (diminution of *Agni*) and *Rasayana* properties may help to overcome tiredness. It enhances *Dhatwagni*, which might improve the absorption of essential nutrients like iodine and support thyroid hormone production. Additionally, it may help balance *Vata* and *Kapha Doshas* and boost overall energy and vitality.

## Discussion on Objective Parameters

### A. TSH Value

In combination with *Kulattha Yusha* (horse gram soup) with *Vidanga Churna*, showed a significantly greater decrease in TSH levels. It increases *Dhatvagni*, removes *Ama* (toxins), clears *Srotorodha*, subsides *Avarana*, and brings harmony, helping in decreasing TSH mentioned in the research study by H. Kanzaria et al (2017).[13] In *Ayurveda*, Thyroxine can be compared to *Kayaagni Amsha*, a component of *Agni*. Additionally, some nutritional analysis studies have found that *Kulattha Yusha* (horse gram soup) contains 6.68% tyrosine of total nitrogen, which supports thyroid hormone production and improves metabolic function. "Assessment of proximate principles of *Kulattha Yusha*" by Dr. Vijethkumar. L. A (2017)[14]

### B. Hemoglobin level

The combined effect of *Kulattha Yusha* (horse gram soup) and *Vidanga Churna* might enhance blood health. *Kulattha Yusha* (horse gram soup) contains 0.0076% iron, which has been found to play a role in thyroid hormone production and improve metabolic function, as noted in the study "Assessment of Proximate Principles of *Kulattha Yusha*" by Dr. Vijethkumar L.A. (2017)[15] supports red blood cell production and overall blood quality due to its rich iron and protein content. It also aids digestion, improves nutrient absorption, and offers detoxifying and anti-inflammatory benefits, contributing to better blood circulation and healing.

*Vidanga* is *Tikshana*, *Ushana*, *Agni Vardhaka*, and *Krimihara*. It might help increase hemoglobin by providing iron, enhancing digestion for better nutrient absorption, and supporting blood purification. *Emblica ribes* are responsible for anti-helminthic activity that can prevent anemia because of worm infestation. As discussed in Preliminary Standardization of *Vidangadya Loha* and *Dhatri Loha* Potential Drug for *Pandu Roga* by Dr. Anita Yadav (2017)[16], by synergistically combining the actions of these drugs, both *Jatharagni* (digestive fire) and *Dhatvagni* (metabolic factors located in *Dhatu*) might be enhanced, potentially leading to improvements in the quality and quantity of *Rasa* and *Rakta Dhatu*. The *Srotovishodhana* properties might help reduce *Srotosanga*, which could enable the *Dhatu*s to nourish all areas of the body more effectively.

## Conclusion

The combined administration of *Kulattha Yusha* (horse gram soup) and *Vidanga Churna* has been demonstrated to be an effective *Pathya* in the management of hypothyroidism. In a study involving 30 subjects, significant improvements were observed in Zulewski's clinical score for hypothyroidism ( $p < 0.001$ ), as well as in objective parameters such as TSH levels and hemoglobin ( $p < 0.001$ ). These results indicate a statistically significant enhancement in the condition. Specifically, 17 subjects exhibited marked improvement, 9 showed moderate improvement, and 4 experienced mild improvement. These findings underscore the potential efficacy of this combination therapy in managing hypothyroidism.

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