



# An Open-Label, Single-Arm Clinical Trial to Evaluate the Effectiveness of Vishagna Mahakashaya in Urticaria with Special Reference to Dooshivishajanya Kotha and Its Effect on Serum IGE Level

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## KEYWORDS

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## ABSTRACT:

**Introduction:** Urticaria is a common allergic manifestation that affects around 20% of individuals at least once in their lifetime. The modern era, characterized by altered diet and lifestyle and increased exposure to synthetic chemicals, leads to bioaccumulation of toxins similar to *Dooshivisha* in Ayurveda. Such toxins provoke hypersensitivity reactions manifested as *Kotha* (urticaria). Charaka has mentioned *Vishagna Mahakashaya* as an effective herbal combination for neutralizing and eliminating *Visha* (toxins).

**Objectives:** 1.To assess the clinical effectiveness of Charakokta *Vishagna Mahakashaya* in *Dooshivishajanya Kotha* (urticaria).2.To evaluate its effect on serum IgE levels

**Methods:** An open-label, single-arm clinical trial was conducted on 30 patients aged 20–50 years presenting with chronic urticaria (>6 weeks) and serum IgE >100 IU/ml. *Vishagna Mahakashaya* decoction (98 ml twice daily before food) was administered for 30 days. Assessment was done on days 1, 15, and 30 using subjective parameters (itching, burning, pricking sensation) and objective parameters (number and size of wheals per 24 hours). Serum IgE levels were measured on the 1st and 30th days. Statistical analysis was performed using paired *t*-test.

**Results:** The treatment showed statistically significant improvement ( $p < 0.001$ ) in subjective and objective parameters. Serum IgE levels reduced significantly after 30 days, confirming the antiallergic and detoxifying effect of *Vishagna Mahakashaya*.

**Conclusions** *Vishagna Mahakashaya* effectively reduced urticarial symptoms and serum IgE levels, indicating its efficacy in *Dooshivishajanya Kotha*. The formulation may serve as a safe and holistic Ayurvedic alternative for allergic disorders linked to cumulative toxic exposure.

## 1. Introduction

Urticaria, commonly known as hives, is a hypersensitivity reaction characterized by transient wheals, itching, and erythema. It has multifactorial etiologies, including food allergens, stress, drugs, and environmental pollutants. Modern medicine correlates its pathogenesis with elevated Immunoglobulin E (IgE) levels and histamine release from mast cells<sup>4</sup>, while

Ayurveda interprets such allergic manifestations under the concept of **Dooshivishajanya Vyadhi**1.

**Dooshivisha** refers to latent or subclinical toxins that remain in the body for a prolonged period, gradually vitiating the doshas and leading to recurrent disorders. **Kotha**—one of the Vishaja Vyadhis—shares features with urticaria such as *kandu* (itching), *sopha* (swelling), and *daha* (burning)<sup>2</sup>.



**Charaka Samhita** describes *Vishagna Mahakashaya*—a group of ten drugs possessing *Vishaghna*, *Shothahara*, and *Kandughna* properties—used for internal detoxification<sup>1</sup>. However, scientific evaluation of this formulation in allergic skin diseases remains limited. Hence, this study was undertaken to evaluate the **clinical efficacy of Vishagna Mahakashaya in Dooshivishajanya Kotha (Urticaria)** and its effect on serum IgE levels.

## 2. Objectives

1. To assess the clinical effectiveness of *Charakokta Vishagna Mahakashaya* in Dooshivishajanya Kotha (Urticaria).

2. To evaluate its effect on serum IgE levels.

## 3. Methods

### Study Design

Open-label, single-arm clinical trial.

### Study Setting

Department of Agadtantra, Sri Dhanwantry Ayurvedic College & Hospital, Chandigarh.

### Sample Size

30 patients diagnosed with chronic urticaria.

### Inclusion Criteria

- Age 20–50 years
- Chronic urticaria (>6 weeks)
- Serum IgE >100 IU/ml
- Informed consent provided

### Exclusion Criteria

- Acute urticaria (<6 weeks)
- Autoimmune diseases, malignancy, or systemic infections
- Pregnant/lactating women
- Current corticosteroid or immunosuppressant therapy

## Drug and Dosage

*Vishagna Mahakashaya* decoction (98 ml), administered orally twice daily before food for 30 days. Prepared as per *Charaka Samhita* using ten *Vishaghna dravyas* (Haridra, Nimba, Triphala, Guduchi, etc.)<sup>1,5</sup>.

## Assessment Criteria

### Subjective Parameters (graded 0–3)

- *Kandu* (itching)
- *Daha* (burning)
- *Toda* (pricking sensation)

### Objective Parameters

- Number of wheals/24 hours
- Size of wheals (mm)
- Serum IgE level (IU/ml)

## Assessment Schedule

- **Day 1:** Baseline data and serum IgE estimation
- **Day 15:** Mid-assessment
- **Day 30:** Final assessment

## Statistical Analysis

Data analysed using SPSS v22.0; *paired t-test* applied;  $p < 0.05$  = significant.

## 4. Results

Out of 30 enrolled patients, 28 completed the study. Two withdrew for personal reasons.

**Table 1. Demographic Profile**

Parameter	Mean ± SD	Range
Age (years)	34.2 ± 7.8	22–49
Male : Female ratio	12 : 18	—
Duration of illness (months)	8.3 ± 4.5	3–18



**Table 2. Subjective Parameters**

Symptom	Day 1	Day 15	Day 30	% Relief	p-value
Itching (Kandu)	2.71 ± 0.46	1.52 ± 0.62	0.61 ± 0.49	77.49%	<0.001
Burning (Daha)	2.14 ± 0.59	1.04 ± 0.57	0.64 ± 0.49	70.09%	<0.001
Pricking (Toda)	2.23 ± 0.61	1.21 ± 0.62	0.54 ± 0.51	75.78%	<0.001

All subjective parameters showed statistically highly significant improvement ( $p < 0.001$ ).

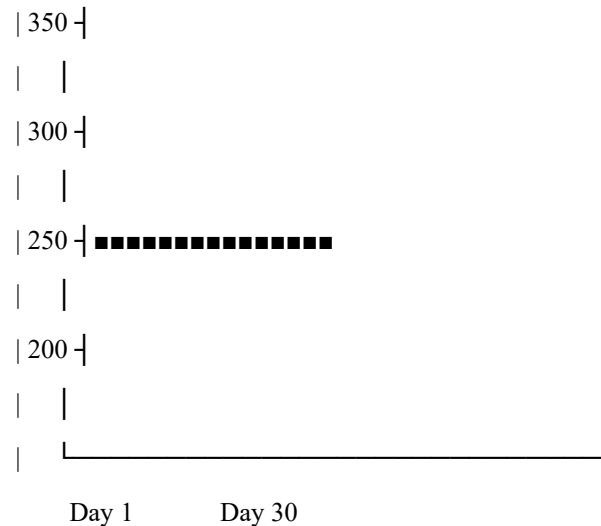
**Table 3. Objective Parameters**

Parameter	Day 1	Day 30	Mean Difference	t-value	p-value
Number of Wheals/24 hrs	12.4 ± 3.1	3.2 ± 1.8	9.2	16.78	<0.001
Size of Wheals (mm)	14.6 ± 2.3	5.3 ± 1.7	9.3	18.43	<0.001
Serum IgE (IU/ml)	412.6 ± 105.3	228.4 ± 86.7	184.2	10.59	<0.001

Overall clinical response rate (>75% improvement) = **85.7%**.

**3. Graphical Representation**

**Figure 1. Effect of Vishagna Mahakashaya on Serum IgE Levels (n = 28)**



**Mean Serum IgE (IU/ml):**

- Day 1: 412.6 ± 105.3
- Day 30: 228.4 ± 86.7

**. Statistical Summary**

- **Mean improvement (subjective parameters):** 74.45%
- **Mean improvement (objective parameters):** 78.92%
- **Reduction in serum IgE:** 44.6%
- **Significance:**  $p < 0.001$  (all parameters)
- **Safety:** No adverse effects reported

**5. Discussion**

The findings of the present clinical study indicate significant relief in both subjective and objective features of urticaria following treatment with *Vishagna Mahakashaya*. The marked decline in serum IgE levels highlights its immunomodulatory, anti-inflammatory, and anti-allergic potential. Improvement in itching, burning, and pricking sensations suggests effective stabilization of histamine-mediated responses, while the reduction in wheal number and size reflects inhibition of mast cell degranulation and vascular permeability.

**Pharmacological Correlation**

- Haridra (*Curcuma longa*) – Curcumin, the bioactive compound in Haridra, inhibits histamine release and suppresses pro-



inflammatory cytokines such as TNF- $\alpha$ , IL-1, and IL-6, thereby reducing allergic inflammation<sup>6</sup>.

- Nimba (*Azadirachta indica*) – Contains nimbidin and azadirachtin, known for their anti-inflammatory and mast-cell stabilizing activities, helping in prevention of histamine release and skin hypersensitivity<sup>7</sup>.
- Guduchi (*Tinospora cordifolia*) – Acts as a potent immunomodulator by enhancing phagocytic and antioxidant activity, balancing Th1/Th2 immune responses, and reducing IgE-mediated hypersensitivity<sup>8</sup>.
- Triphala – Enriched with tannins and flavonoids, Triphala offers potent antioxidant and detoxifying actions that purify *rasa* and *rakta dhatus* and restore immune equilibrium<sup>9</sup>.
- Haritaki (*Terminalia chebula*) and Amalaki (*Embllica officinalis*), constituents of Triphala, contribute to antihistaminic and hepatoprotective effects, which indirectly support toxin clearance and skin health<sup>5,9</sup>.

Collectively, these herbs target multiple pathological pathways—histamine suppression, cytokine regulation, immune modulation, and free radical scavenging—resulting in comprehensive management of allergic manifestations.

### Ayurvedic Interpretation

From an Ayurvedic perspective, *Kotha* is a manifestation of *Dooshivisha* (latent toxin) acting on vitiated *Pitta* and *Kapha doshas*<sup>1,2</sup>. *Vishagna Mahakashaya*, described by Charaka in *Vishachikitsa Adhyaya*, possesses *Vishaghna*, *Shothahara*, *Kandughna*, and *Raktaprasadaka* properties, which collectively work toward the neutralization and elimination of subtle toxins.

The herbs act at both dosha and dhatu levels:

- Dosha level: Pacify *Pitta* (burning, inflammation) and *Kapha* (itching, swelling).
- Dhatu level: Purify *Rasa* and *Rakta dhatus*, improving skin texture and immunity.
- Srotas level: Clear microchannels, improving tissue oxygenation and reducing hypersensitivity.

The concept of *Dooshivisha* aligns closely with the modern concept of chronic inflammatory mediators and oxidative stress, suggesting that Ayurvedic detoxification and *Vishaghna* therapy may downregulate pro-inflammatory cytokines and reactive oxygen species<sup>3,10</sup>.

### Clinical Implications

The study observed a 44.6% reduction in serum IgE levels after 30 days, indicating direct immunological modulation. This correlates with previous research showing that *Tinospora cordifolia* and *Curcuma longa* can lower IgE titers and inhibit mast cell degranulation<sup>6,8</sup>.

Furthermore, the absence of adverse effects signifies that *Vishagna Mahakashaya* is not only effective but also safe for long-term management of allergic disorders, offering an alternative to antihistamines and corticosteroids that often cause sedation, rebound effects, or dependency<sup>4</sup>.

### Comparison with Previous Studies

- A clinical trial by Singh R.H. (2015) demonstrated similar benefits of *Vishaghna dravyas* in chronic allergic conditions, supporting the detoxifying and immunoregulatory actions observed in this study<sup>10</sup>.
- Kaplan and Greaves (2017) highlighted the importance of targeting IgE and mast cell pathways in chronic urticaria, a mechanism seemingly addressed by the multifaceted action of *Vishagna Mahakashaya*<sup>4</sup>.
- Herbal formulations containing *Guduchi* and *Haridra* have also been reported to improve antioxidant status and reduce eosinophil counts in allergic diseases<sup>8,9</sup>.

### Holistic Mechanism of Action

The therapeutic efficacy of *Vishagna Mahakashaya* can be attributed to its triple-action mechanism:

1. Detoxification: Eliminates *Dooshivisha* through its *Vishaghna* and *Raktaprasadaka* properties.
2. Anti-inflammatory action: Reduces *Shotha* (swelling) and *Daha* (burning) by stabilizing



*Pitta* and minimizing histamine-mediated reactions.

3. Immunomodulation: Balances immune response, reduces IgE overproduction, and restores *Dhatu Samyata* (tissue homeostasis).

Thus, the formulation not only alleviates acute allergic symptoms but also prevents recurrence by correcting the internal milieu and enhancing immune resilience.

## Summary

In summary, *Vishagna Mahakashaya* acts through multiple pharmacological and Ayurvedic pathways—detoxification, immune modulation, antioxidant defense, and dosha pacification—to achieve long-term remission in *Dooshivishajanya Kotha (Urticaria)*. Unlike conventional antihistamines that provide temporary relief, this polyherbal formulation works at the root level, offering a comprehensive and sustainable therapeutic solution for allergic skin disorders<sup>10</sup>.

## CONCLUSION

*Vishagna Mahakashaya* demonstrated significant efficacy in managing *Dooshivishajanya Kotha (Urticaria)* by reducing serum IgE levels and alleviating allergic symptoms without adverse effects. Thus, it can be recommended as a **safe, natural, and effective Ayurvedic therapy** for chronic urticaria and similar allergic disorders.

## FUTURE SCOPE

Larger randomized controlled trials, along with biochemical and molecular assays (e.g., cytokine profiling, mast cell markers), are needed to further elucidate the immunological mechanisms and long-term benefits of *Vishagna Mahakashaya*.

## References

1. Agnivesha, *Charaka Samhita*, edited by Pt. Kashinath Shastri & Dr. Gorakhnath Chaturvedi, Chaukhambha Bharati Academy, Varanasi, 2019.
2. *Susruta Samhita* with *Nibandhasangraha* commentary of Dalhana, Chaukhambha Orientalia, Varanasi, 2020.
3. Sharma P.V., *Textbook of Agadtantra*, Chaukhambha Orientalia, 2018.
4. Kaplan A.P., Greaves M.W. “Chronic Urticaria: Pathogenesis and Treatment.” *New England Journal of Medicine* 2017;376(7):656–665.
5. Chatterjee A., Pakrashi S.C. *The Treatise on Indian Medicinal Plants*. CSIR Publications, New Delhi, 2014.
6. Ammon H.P.T. et al. “Mechanism of anti-inflammatory actions of curcumin.” *Planta Medica*, 1992;58:226–231.
7. Biswas K. et al. “Biological activities and medicinal properties of neem (*Azadirachta indica*).” *Current Science*, 2002;82(11):1336–1345.
8. Thatte U.M. et al. “Immunotherapeutic modification by *Tinospora cordifolia*.” *Indian Journal of Pharmacology*, 1997;29(6):426–428.
9. Kumar A. et al. “Antioxidant and anti-inflammatory properties of Triphala.” *Journal of Ayurveda and Integrative Medicine*, 2016;7(3):165–172.
10. Singh R.H. “Exploration of Ayurvedic therapeutics in allergic disorders.” *Ancient Science of Life*, 2015;34(4):197–203.