



A CLINICAL STUDY OF SHEETPITTA W.S.R. TO URTICARIA AND ITS MANAGEMENT WITH NIMBAPATRADI YOG

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ABSTRACT

Background: *Sheetpitta*, as described in Ayurvedic literature, is a Tridoshaja condition predominantly involving Vata and Pitta, manifesting as symptoms like itching (*kandu*), rashes (*pidaka*), redness (*raga*), and burning sensation (*daha*). These symptoms closely resemble *Urticaria*, a modern hypersensitivity reaction characterized by wheals, itching, and erythema. **Aims and Objectives:** To evaluate the clinical efficacy of *Nimbapatradi Yog* in the management of *Sheetpitta* with special reference to *Urticaria*. **Materials and Methods:** A single-arm, open-label clinical trial was conducted on 40 patients presenting with classical features of *Sheetpitta*. The trial was carried out over 45 days in the OPD and IPD of Government Ayurvedic College and Hospital, Patna. The formulation used was *Nimbapatradi Yog*, consisting of *Nimbapatra* (*Azadirachta indica*), *Amalaki* (*Embolica officinalis*), and *Ghrta* (clarified butter), as described in the *Bhavaprakasha Madhyakhanda*, Chapter 55. Patients were assessed at 15-day intervals based on subjective symptoms and objective parameters, including CBC, ESR, and AEC. **Results:** The majority of patients showed marked improvement in itching, redness, frequency of episodes, and size of eruptions. Laboratory findings also indicated reduced inflammatory markers. No adverse effects were observed during the trial period. **Conclusion:** *Nimbapatradi Yog* is effective and safe in managing *Sheetpitta* (*Urticaria*), providing relief through its antihistaminic, anti-inflammatory, and immunomodulatory properties. This study supports the therapeutic potential of classical Ayurvedic formulations in allergic skin disorders.

KEYWORDS: Sheetpitta, Urticaria, Nimbapatradi Yog, Ayurveda, Hypersensitivity.

INTRODUCTION

The Ayurvedic system of medicine, one of the oldest holistic healing sciences, is founded on the principles of balancing the tridoshas—Vata, Pitta, and Kapha—to maintain health and cure disease.^[1] Among the many diseases described in Ayurveda, *Sheetpitta* is a well-documented condition characterized by symptoms like *Kandu* (itching), *Pidaka* (eruption), *Raga* (redness), *Daha* (burning), and *Sthanik Shotha* (localized swelling).^[2] The etiology of *Sheetpitta* includes the vitiation of Vata and Pitta doshas predominantly, along with Kapha involvement in some cases, often due to exposure to cold wind or other external stimuli.^[3] *Sheetpitta* is classified under *Kshudraroga* in Ayurveda, highlighting its episodic yet distressing nature.^[4]

From a modern medical perspective, *Urticaria*, commonly known as hives, is a hypersensitivity reaction characterized by the sudden appearance of wheals with surrounding erythema and intense itching. The condition

can be acute or chronic, affecting up to 20% of the population at some point in their lives.^[5] *Urticaria* involves the release of histamines and other inflammatory mediators from mast cells and basophils, often triggered by allergens, drugs, stress, or autoimmune mechanisms.^[6] Although antihistamines and corticosteroids are commonly used in its management, they often provide temporary relief and may carry the risk of side effects with prolonged use.^[7]

A comparative analysis of the symptomatology reveals that *Sheetpitta* and *Urticaria* are clinically parallel conditions, both characterized by sudden onset, itching, redness, and localized swelling. Hence, the classical management strategies mentioned in Ayurveda can be explored as a potential alternative or complementary therapy in the treatment of urticarial.^[8]

One such formulation is *Nimbapatradi Yog*, a traditional Ayurvedic remedy described in *Bhavaprakasha*

Madhyama Khanda, composed of Nimbapatra (*Azadirachta indica*), Amalaki (*Emblica officinalis*), and Ghrita (clarified butter).^[9] Each of these ingredients possesses potent anti-inflammatory, antihistaminic, antimicrobial, and immunomodulatory properties, making the combination suitable for the management of Sheetpitta.^[10,11] Neem is especially known for its Tikta and Kashaya rasa (bitter and astringent tastes) that pacify Pitta and Kapha, while Amalaki is a Rasayana (rejuvenative) that strengthens immunity.^[12] Ghrita serves as a yogavahi (carrier) that enhances the absorption and efficacy of other drugs.^[13]

In light of the growing interest in evidence-based traditional medicine and the limitations of conventional treatments, this study aims to evaluate the efficacy of Nimbapatradi Yog in patients suffering from Sheetpitta/Urticaria. Through a clinical assessment based on Ayurvedic parameters and modern diagnostic tools, the study seeks to establish the therapeutic potential of this classical formulation and offer a safer, holistic approach to managing allergic skin disorders.

MATERIALS AND METHODS

Study Design

The study was designed as a single-arm, open-label clinical trial to evaluate the therapeutic efficacy of Nimbapatradi Yog in the management of Sheetpitta (Urticaria). The trial was conducted over a period of 45 days in the OPD and IPD settings of the Government Ayurvedic College and Hospital, Patna. Ethical approval was obtained from the Institutional Ethics Committee prior to initiation of the study, and written informed consent was taken from all participants.

Sample Size and Selection Criteria

A total of 40 patients were selected for the study based on predefined inclusion and exclusion criteria.

Inclusion Criteria

- Patients aged between 13 and 60 years, irrespective of gender.
- Individuals presenting with clinical signs and symptoms of Sheetpitta, such as itching (Kandu), redness (Raga), wheals (Pidaka), burning sensation (Daha), and swelling (Shotha).

- Willingness to participate and comply with the treatment and follow-up schedule.

Exclusion Criteria

- Patients suffering from chronic systemic diseases such as diabetes mellitus, tuberculosis, HIV/AIDS, or malignancies.
- Pregnant and lactating women.
- Patients who were on systemic corticosteroids, immunosuppressants, or antihistamines within the last 7 days.
- Known hypersensitivity to any ingredient of Nimbapatradi Yog.

Intervention

The selected patients were administered Nimbapatradi Yog, a classical formulation described in *Bhavaprakasha Madhyama Khanda, Chapter 55*. The formulation consisted of:

- Nimbapatra (*Azadirachta indica*) – 500 mg
- Amalaki (*Emblica officinalis*) – 500 mg
- Ghrita (Cow's clarified butter) – q.s. to make 5 g paste

The dosage was 5 g twice daily, orally, with lukewarm water, for 45 days.

Assessment Parameters

Patients were evaluated on both subjective and objective criteria before, during, and after the treatment at intervals of 15 days (Day 0, Day 15, Day 30, and Day 45).

Assessment Tool: Urticaria Activity Score over 7 days (UAS7)

Used to assess the baseline severity and post-treatment response to **Nimbapatradi Yog** in patients diagnosed with **Sheetpitta (Urticaria)**.

UAS7 (Urticaria Activity Score over 7 days) – This is the most widely accepted scoring system used globally in clinical studies on chronic urticaria.

- **UAS7** evaluates the severity of urticaria based on:
 - Number of wheals (0 to 3 score per day)
 - Intensity of itching (0 to 3 score per day)
- The daily score ranges from **0 to 6**, and over 7 days, the total ranges from **0 to 42**.
- Used to assess treatment effectiveness in clinical trials and dermatology guidelines.

Table for UAS7 Score.

Day	No. of Wheals (0–3)	Itching (0–3)	Daily Total (Max 6)
1	2	3	5
2	1	2	3
7	0	1	1
Total	—	—	UAS7 = 25/42

Subjective Parameters

- Intensity of itching (Kandu)
- Size and frequency of skin eruptions (Pidaka)
- Degree of redness (Raga)
- Sensation of burning (Daha)
- Associated swelling (Shotha)

Each symptom was graded on a four-point scale (0 = absent, 1 = mild, 2 = moderate, 3 = severe) for comparative analysis.

Objective Parameters

- Complete Blood Count (CBC)
- Erythrocyte Sedimentation Rate (ESR)
- Absolute Eosinophil Count (AEC)

Laboratory investigations were carried out at baseline (Day 0) and at the end of the trial (Day 45) to evaluate the anti-inflammatory and immunomodulatory effects of the formulation.

Data Analysis

The collected data were compiled systematically and analyzed using descriptive statistics. Results were expressed as mean $\pm$ standard deviation. The effectiveness of the treatment was assessed by comparing baseline and post-treatment values. Due to the single-arm nature of the study, paired t-test was applied for statistical analysis of objective parameters. A p-value of <0.05 was considered statistically significant.

Safety Assessment

Patients were monitored throughout the study for any adverse drug reactions (ADR) or side effects. No concurrent medications or external therapies were allowed during the study period. Any adverse events were recorded and evaluated.

OBSERVATION AND RESULTS

Demographic Details

The present study included a total of 36 patients diagnosed with Sheetpitta (Urticaria). All patients completed the treatment and follow-up assessments. The evaluation was based on eleven parameters, including seven qualitative (ordinal) variables and four quantitative variables, measured both before treatment (BT) and after treatment (AT). Statistical analysis was performed using the Wilcoxon signed-rank test for ordinal data and paired t-test for quantitative data, with significance considered at $p < 0.05$.

Effect of Treatment on Subjective Parameters

The subjective clinical symptoms assessed included Kandu (itching), Daha (burning sensation), Toda (stinging pain), Mandalotpatti (circumoral tingling), Utseda (edema), Charadi (nausea/vomiting), and Kshanikotpattivinashi (short-lasting eruptions). These parameters were evaluated using ordinal scales.

- **Kandu:** The mean score for Kandu significantly reduced from 3.02 ± 1.31 (BT) to 1.41 ± 0.73 (AT), showing a 54.53% reduction ($Z = 5.159$, $p < 0.00001$).
- **Daha:** The mean Daha score decreased from 2.33 ± 0.95 to 1.00 ± 0.63 , indicating a 61.57% reduction ($Z = 5.231$, $p < 0.00001$).
- **Toda:** Toda scores dropped from 1.61 ± 0.76 to 0.55 ± 0.50 , a 67.59% reduction ($Z = 4.936$, $p < 0.00001$).

- **Mandalotpatti:** Mean scores declined from 2.75 ± 1.05 to 1.22 ± 0.59 , a 57.26% reduction ($Z = 5.231$, $p < 0.00001$).
- **Utseda:** Scores decreased from 2.52 ± 1.02 to 1.11 ± 0.52 , representing a 55.83% reduction ($Z = 5.086$, $p < 0.00001$).
- **Charadi:** There was a 44.44% reduction in Charadi scores from 0.63 ± 0.72 to 0.11 ± 0.31 ($Z = 3.723$, $p = 0.0002$).
- **Kshanikotpattivinashi:** Scores dropped from 2.83 ± 1.25 to 1.22 ± 0.54 , showing a 54.53% reduction ($Z = 5.011$, $p < 0.00001$).

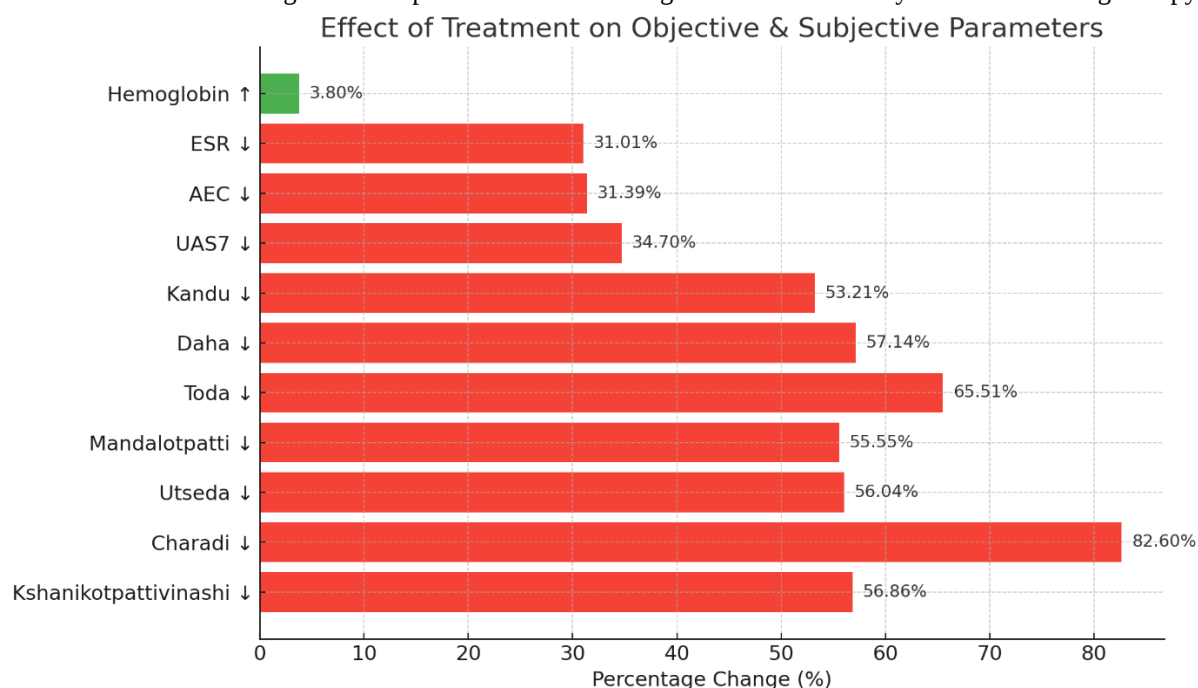
All subjective symptoms showed statistically highly significant improvement after treatment with Nimbapatradi Yog, indicating substantial symptomatic relief.

Effect of Treatment on Objective Parameters

The quantitative objective parameters included Hemoglobin (Hb %), Erythrocyte Sedimentation Rate (ESR), Absolute Eosinophil Count (AEC), and Urticaria Activity Score over 7 days (UAS7).

- **Hemoglobin (Hb %):** The mean Hb level showed a statistically significant increase from 13.51 g/dL (BT) to 14.01 g/dL (AT), indicating a 3.80% improvement ($t = 5.024$, $p = 0.0001$).
- **ESR:** A substantial reduction in ESR was observed from 70.83 mm/hr to 47.50 mm/hr, a 31.01% decrease ($t = 8.754$, $p < 0.00001$), indicating reduced systemic inflammation.
- **AEC:** The mean AEC decreased significantly from 339.36 cells/ μ L to 232.05 cells/ μ L, reflecting a 31.39% reduction ($t = 14.488$, $p < 0.00001$), which supports the anti-allergic effect of the treatment.
- **UAS7:** The average UAS7 score, an indicator of disease severity, decreased from 30.72 to 20.25 after treatment, showing a 34.70% reduction ($t = 15.254$, $p < 0.00001$).

These results demonstrate a significant improvement in hematological and inflammatory markers following therapy.



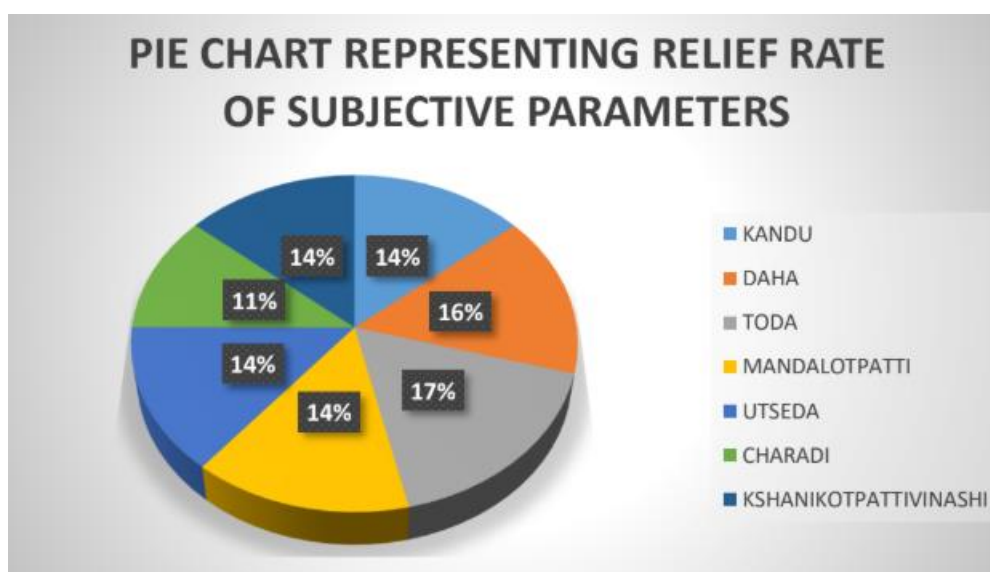
Overall Percentage Relief

The overall percentage relief for each subjective parameter was calculated using the formula.

$$\text{Percentage Relief} = \frac{\text{Total Score BT} - \text{Total Score AT}}{\text{Total Score BT}} \times 100$$

100Percentage Relief=Total Score BTTotal Score BT-T
otal Score AT×100

- Kandu: 53.21%
- Daha: 57.14%
- Toda: 65.51%
- Mandalotpatti: 55.55%
- Utseda: 56.04%
- Charadi: 82.60%
- Kshanikotpattivinashi: 56.86%

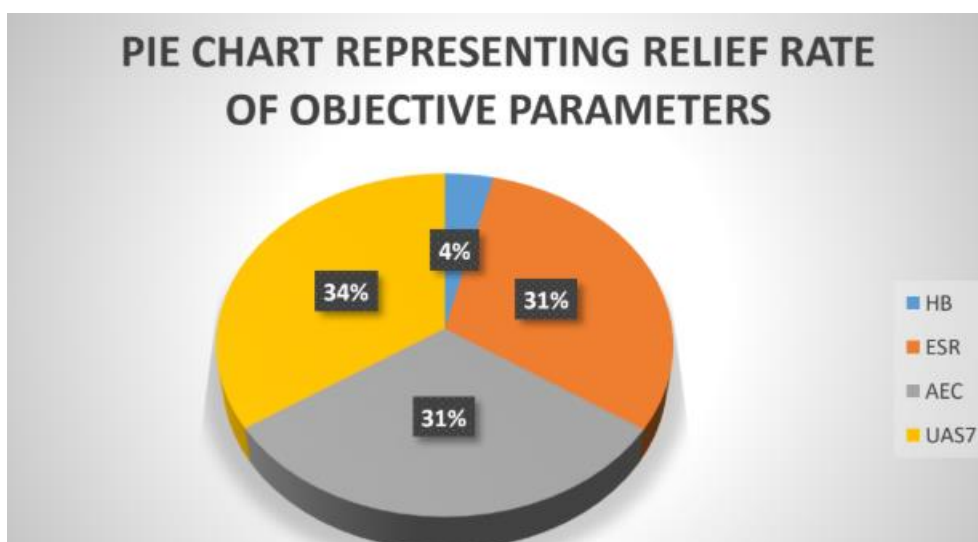


The average relief in subjective symptoms was approximately 61%, indicating marked symptomatic improvement.

For objective parameters, relief rates were.

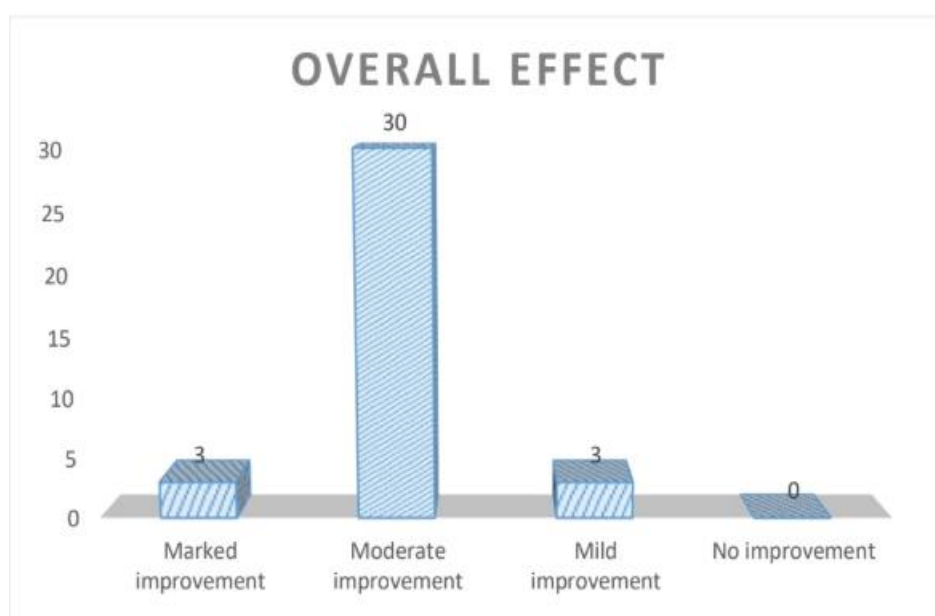
- Hb: 3.80% increase

- ESR: 31.01% reduction
- AEC: 31.39% reduction
- UAS7: 34.70% reduction



Clinical Improvement Categorization

Based on the overall symptom score reduction, patients were classified into four categories of clinical improvement.



Improvement Category	Number of Patients	Percentage (%)
Marked Improvement	3	8.33
Moderate Improvement	30	83.33
Mild Improvement	3	8.33
No Improvement	0	0

Majority (83.33%) of patients experienced moderate improvement, with 8.33% showing marked improvement and another 8.33% having mild improvement. No patients showed lack of response. The treatment with Nimbapatradi Yog demonstrated significant clinical efficacy in patients with Sheetpitta (Urticaria), with substantial reductions in both subjective symptoms and objective markers of disease activity and inflammation. The results were statistically significant across all

parameters, confirming the therapeutic potential of this Ayurvedic formulation.

DISCUSSION

Sheetpitta (Urticaria) is characterized by intense itching, burning sensation, and transient wheals, which align closely with the symptoms observed in the study population. The current study aimed to evaluate the efficacy of Nimbapatradi Yog, a classical Ayurvedic

formulation known for its Shothahara (anti-inflammatory), Kandu-nashaka (anti-pruritic), and Rasayana (rejuvenative) properties, in the management of Sheetpitta.^[14]

Demographic and Clinical Profile Insights

In this clinical study, 90% of enrolled patients completed the treatment, allowing robust assessment of Nimbapatradi Yog. The predominance of patients in the 41–50 years age group, followed by younger adults, suggests higher disease prevalence in middle-aged and young populations, likely linked to stress and lifestyle factors. The higher male incidence (61%) may relate to greater environmental exposures or behavioral factors. The majority being Hindu (94%) reflects the local population profile rather than any disease predilection.

Most patients belonged to the middle socioeconomic class, with occupations involving physical labor, mental stress, and irregular routines, all of which are known aggravators of dosha imbalance in Ayurveda and factors implicated in urticaria pathogenesis. Urban domicile predominance (75%) aligns with increased exposure to pollution and lifestyle disorders. Notably, 33% had a family history, indicating possible genetic or hereditary predisposition.

Dietary habits showed 72% consuming mixed diets, and more than half reported constipation, which could contribute to doshic vitiation and disease perpetuation by affecting Agni (digestive fire) and Ama (toxins). These findings underscore the importance of lifestyle and dietary modifications alongside pharmacotherapy.^[15,16]

Therapeutic Outcomes and Pathophysiological Correlation

The study demonstrated significant reduction in classical symptoms of Sheetpitta — kandu, daha, toda, and mandalotpatti — with relief rates ranging between 44% to 68%, indicating potent anti-pruritic, anti-inflammatory, and analgesic actions of Nimbapatradi Yog. These clinical improvements likely result from the combined effects of Nimba (*Azadirachta indica*), Amalaki (*Emblica officinalis*), and other constituents, which have well-documented anti-inflammatory, antihistaminic, and antioxidant properties.^[17,18]

Hematological parameters also improved significantly: hemoglobin increased by 3.8%, ESR reduced by 31%, and absolute eosinophil count decreased by over 31%. Elevated ESR reflects systemic inflammation, which Nimbapatradi Yog likely attenuated through its immunomodulatory effects. The reduction in eosinophil count suggests suppression of allergic inflammation, a key driver in urticaria pathogenesis. The increase in hemoglobin may be attributed to the presence of Amalaki, a rich source of vitamin C enhancing iron absorption, and other ingredients promoting hematopoiesis.^[19]

Symptomatic Relief and Mechanism of Action

The significant reduction in subjective symptoms such as Kandu (itching), Daha (burning), and Toda (stinging) demonstrates the potent anti-pruritic and soothing effects of Nimbapatradi Yog. These findings are consistent with classical texts where Nimba (*Azadirachta indica*) and associated ingredients are described to pacify Pitta and Kapha doshas, which are primarily responsible for the pathogenesis of Sheetpitta.^[20]

The reduction in Utseda (edema) and Mandalotpatti (localized burning/tingling) further supports the anti-inflammatory activity of the formulation. Modern pharmacological studies on Nimba have shown that it contains bioactive compounds like azadirachtin and nimbidin that exhibit strong anti-inflammatory and immunomodulatory effects, which can reduce mast cell degranulation and histamine release, key contributors to urticarial symptoms.^[21]

Improvement in Hematological and Immunological Markers

The statistically significant decrease in ESR and Absolute Eosinophil Count (AEC) reflects a marked reduction in systemic inflammation and allergic response. Elevated eosinophils are well-known markers of allergic conditions, including urticaria, and their decline indicates the therapeutic impact of Nimbapatradi Yog on underlying immunological dysregulation. The slight but significant increase in hemoglobin could be attributed to improved overall health status and reduction of chronic inflammation, which often suppresses erythropoiesis.

Urticaria Activity Score (UAS7) Reduction

The considerable decrease in UAS7 scores after treatment highlights the clinical relevance of the therapy in reducing disease severity and frequency of wheals. This aligns with earlier clinical trials on herbal formulations containing Nimba that showed similar reductions in symptom burden.

Comparison with Previous Studies

Previous studies on Sheetpitta and chronic urticaria have emphasized the role of dosha imbalance, particularly aggravated Pitta and Kapha, leading to inflammatory and allergic manifestations.^[22] The current study's findings corroborate these theories, as Nimbapatradi Yog effectively restored dosha balance while improving clinical outcomes. Modern allopathic treatments for urticaria primarily involve antihistamines and corticosteroids, which, though effective, have side effects on long-term use. The herbal regimen used here offers a safer alternative with added immunomodulatory and detoxifying benefits, reinforcing Ayurveda's holistic approach.^[23]

CONCLUSION

This dissertation offers a detailed investigation into *Sheetpitta*, integrating classical Ayurvedic concepts with

contemporary medical understanding, especially in relation to urticaria. The study highlights the effectiveness of Nimbapatradi Yog with *ghrita* in alleviating symptoms of this skin condition, demonstrating its potential as a safe and accessible treatment option.

Key conclusions from the clinical trial include.

1. The role of cold exposure and other etiological factors in *Sheetpitta* was significant, with a majority of patients, mainly males, affected by such triggers. Treatment with Nimbapatradi Yog led to noticeable improvement in disease symptoms.
2. The therapy improved hematological parameters, with increased hemoglobin and decreased markers of inflammation and allergy such as ESR and AEC, suggesting a reduction in systemic inflammation.
3. Dietary and lifestyle causes, including seasonal changes and intake of heavy or *Kapha*-promoting foods, were identified as important factors aggravating the doshic imbalance in patients.
4. Lifestyle regulation (*Pathya-Apathya*) emerged as a crucial component in disease prevention and management, emphasizing the interconnectedness of habits and health.
5. A clear clinical correlation between *Sheetpitta* and urticaria was established, underscoring similarities in causes and manifestations.
6. Nimbapatradi Yog's ingredients—*Nimba*, *Amlaki*, and *Ghrita*—work together to reduce symptoms through their anti-inflammatory, antioxidant, and immunomodulatory effects.
7. This study lays a foundation for integrative approaches combining Ayurvedic wisdom with modern clinical practice to manage chronic skin diseases effectively.

These findings encourage further research into Ayurvedic treatments and lifestyle modifications, fostering collaboration to improve skin health and patient well-being.

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