

AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE COMBINED EFFECT OF SADHYOVAMANA, GUDADEEPYAKA AND NISHOTTAMADI KASHAYA IN THE MANAGEMENT OF SHEETAPITTA VIS-À-VIS URTICARIA

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DOI: <https://doi.org/10.5281/zenodo.23828944>



How to cite this Article: Dr. Megha M. Pujari^{*1}, Dr. Ananta S. Desai², Dr. Mythrey R. C.³ (2026). An open Label Single Arm Clinical Study To Evaluate The Combined Effect of Sadhyovamana, Gudadeepyaka And Nishottamadi Kashaya In The Management Of Sheetapitta Vis-À-Vis Urticaria. World Journal of Pharmaceutical and Medical Research, 12(11), 269-278. This work is licensed under Creative Commons Attribution 4.0 International license.

Article Received on 22/09/2026

Article Revised on 12/10/2026

Article Published on 01/11/2026

ABSTRACT

Background: *Sheetapitta* is a *Tridoshaja Vyadhi* predominantly involving *Vata* and *Kapha* with *Pitta*. It closely resembles Urticaria, a hypersensitivity disorder characterized by recurrent wheals, pruritus, and erythema, affecting quality of life. Conventional treatment mainly provides symptomatic relief with recurrence. Ayurveda recommends *Shodhana* and *Shamana* therapies. Hence, this study evaluated the combined effect of *Sadhyovamana*, *Gudadeepyaka*, and *Nishottamadi Kashaya* in *Sheetapitta vis-à-vis* Urticaria. **Objectives:** To evaluate the Combined efficacy of *Sadhyovamana* followed by *Gudadeepyaka* and *Nishottamadi Kashaya* in reducing clinical manifestations and improving the Urticaria Activity Score (UAS). **Materials and Methods:** An open-label single-arm clinical study was conducted on 33 subjects diagnosed with *Sheetapitta vis-à-vis* Urticaria, with 31 completing the trial. Patients underwent *Sadhyovamana* followed by *Gudadeepyaka* and *Nishottamadi Kashaya*. Assessments were performed on Days 0, 3, 31, and 45. Outcomes were evaluated using UAS and symptom scores for *Varati-Damshtravat Shotha*, *Kandu*, *Toda*, *Daha*, and associated symptoms. Statistical analysis was performed using nonparametric tests. **Results:** The intervention produced highly significant reductions in UAS and symptom scores ($p < 0.001$). Marked improvement from Day 3 was sustained throughout follow-up. Relief was noted in wheals, pruritus, burning, and pricking pain. Most participants experienced improvement without serious adverse events. **Conclusion:** The combined administration of *Sadhyovamana*, *Gudadeepyaka*, and *Nishottamadi Kashaya* was safe and effective in managing *Sheetapitta vis-à-vis* Urticaria. The treatment provided rapid symptomatic relief, reduced disease activity, and maintained clinical improvement during follow-up, supporting its potential as an Ayurvedic therapeutic approach in this clinical study.

KEYWORDS: *Sheetapitta*; Urticaria; *Sadhyovamana*; *Gudadeepyaka*; *Nishottamadi Kashaya*; *Shodhana* Therapy; Ayurveda; Urticaria Activity Score (UAS); *Kandu*; *Varati-Damshtravat Shotha*.

INTRODUCTION

The incidence of allergic disorders is increasing in the present era, attributed to changing lifestyles, environmental pollution, unhealthy dietary habits, stress, irregular sleep, processed and incompatible foods, and increased allergen exposure. *Sheetapitta vis-à-vis* Urticaria is a commonly encountered allergic skin disorder that significantly affects quality of life.

According to Ayurveda, *Sheetapitta* is a *Tridoshajanya Vyadhi* manifested in the skin and can affect individuals of all age groups. Exposure to cold breeze aggravates *Vata* and *Kapha*, which associate with *Pitta* and produce symptoms such as *Varatidamshtravat Shotha*, *Kandu*, *Toda*, *Daha*, *Chardi*, and *Jwara*. *Sheetapitta* and *Udarda* are considered synonyms by Madhavakara.^[1] Its clinical presentation closely resembles urticaria, characterized by transient, pruritic wheals with surrounding erythema, usually lasting less than 24 hours.^[2] Urticaria is classified

as acute when lasting less than 6 weeks and chronic when persisting beyond 6 weeks.^[3] It affects 15 to 20% of people at some point in their life. With peak incidence in third decade, it tends to be more prevalent in females than males.^[4]

Contemporary management primarily involves trigger avoidance and pharmacotherapy, particularly antihistamines and glucocorticoids, which may provide symptomatic relief but can require prolonged use and may be associated with adverse effects. Ayurveda recommends *Shodhana* and *Shamana* therapies, including *Abhyanga*, *Seka*, *Ashu Vamana*, *Virechana*, *Lepa*, and *Shamanoushadhi*.^[5]

Considering the acute onset of *Sheetapitta*, *Sadhyovamana* may facilitate prompt elimination of aggravated *Kapha*. *Gudadeepyaka Churna*, containing *Guda* and *Deepyaka*, and *Nishottamadi Kashaya*, indicated in *Kushta*,^[6] were selected as adjunctive therapies. The present study was undertaken to evaluate their combined effect in *Sheetapitta* vis-à-vis Urticaria using Urticaria Activity Score and symptom scoring at baseline, after *Sadhyovamana* (Day 3), after treatment (Day 31), and follow-up (Day 45).

OBJECTIVE OF THE STUDY

To evaluate the combined effect of *Sadhyovamana*, *Gudadeepyaka* and *Nishottamadi Kashaya* in the management of *Sheetapitta* Vis-à-vis Urticaria.

MATERIAL AND METHODS

Study design

A Single arm clinical study with pre and post-test design.

Source of data

Minimum of 33 subjects were included in the study. Subjects were incidentally selected from OPD & IPD of Government Ayurveda Medical College and Hospital, Mysuru and Government Hi-Tech Panchakarma Hospital, Mysuru.

Intervention

Abhyanga and Sweda- Sarvanga Abhyanga with Mahamarichyadi taila followed by bashpa Sweda as purvakarma on the day of *sadhyovamana* procedure.

Sadhyovamana: Conducted in the morning hours during *Kaphakala* in empty stomach.

- *Akanthapana* with *Ksheera*,
- *Vamaka dravya*-*Patola*, *Nimba*, *Vasa Kashaya* 70-100ml
- *Vamanopaga Dravya*-*Yashtimadhu phanta* and *Sukoshna Lavanambu*.

Shamanoushadis

- *Gudadeepyaka churna* -12gm per day in two equally divided dose during morning and night with warm water after food for 28 days after *Sadhyovamana*.

- *Nishottamadi kashaya* -40ml per day in two equally divided dose during morning and night with equal quantity of warm water after food for 28 days after *Sadhyovamana*.

INCLUSION CRITERIA

1. Subjects of all gender of age group between 18 to 50 years.
2. Subjects with the signs and symptoms of *Sheetapitta* vis-à-vis Urticaria were included.
3. Subjects with Urticaria Activity score - UAS 1-6 were included.
4. Both fresh cases and treated cases of *Sheetapitta* vis-à-vis Urticaria were included.

EXCLUSION CRITERIA

1. Subjects diagnosed with Urticarial vasculitis, Tuberculosis, HIV, Viral infections, Carcinoma and other Skin infections were excluded.
2. Subjects with Uncontrolled Diabetes Mellitus (RBS>250mg/dl), Uncontrolled Hypertension (BP>140/90mmhg), Renal disorders and or other systemic illness which might interfere with the course of treatment were excluded.
3. Pregnant women and lactating mother were excluded.
4. Subjects unfit for *Sadhyovamana* procedure were excluded.

DIAGNOSTIC CRITERIA

The Diagnosis was be done based on the *Lakshanas* of *Sheetapitta* vis-à-vis Urticaria.

ASSESSMENT

Assessment schedule

In this study, total 4 assessments were done.

- ☐ First assessment: Before starting the intervention (0th day)
- ☐ Second assessment: After *sadhyovamana* (3rd day)
- ☐ Third assessment: After completion of intervention (31st day)
- ☐ Follow up – After 15 days of completion of intervention.

Assessment Criteria

- **Primary assessment- Urticaria Activity Score (UAS) – Scoring 0-6^[7]**
- **Secondary assessment- Symptom scoring^[8]**

Varatidashtravat shotha (Wheals)	Score	Chardi (Vomiting)	Score
No Wheals	0	No attacks	0
Wheals on 25% of skin	1	Mild (1 episode/week)	1
Wheals on upto 50% of skin	2	Moderate (2-3 episode/week)	2
Wheals on >50% of skin	3	Severe (>3 episode/week)	3
Kandu (Pruritus)	Score	Jwara (Fever)	Score
No pruritis	0	No fever	0
Mild pruritis	1	Mild fever	1
Moderate pruritis	2	Moderate fever	2
Severe Pruritis.	3	Severe fever	3
Vidaha (Burning Sensation)	Score	Toda (Pricking Sensation)	Score
No burning sensation	0	No Pricking sensation	0
Mild burning sensation	1	Mild Pricking sensation	1
Moderate burning sensation	2	Moderate Pricking sensation	2
Severe burning sensation	3	Severe Pricking sensation	3

Frequency of Attacks	Score
No attacks	0
Mild (1 episode/week)	1
Moderate (2-3 episode/week)	2
Severe (>3 episode/week)	3

STATISTICAL METHODS

The result was compared and analysed statistically by using the following statistical methods:

Descriptive statistics- Mean (SD), Median (IQR), Standard deviation, Percentile.

Inferential testing – Wilcoxon matched pairs test, independent t Test.

0.0001) and Day 45 (56.96% reduction, $p = 0.0001$). However, comparisons between subsequent assessment points were statistically insignificant ($p > 0.05$), indicating that the initial improvement achieved by *Sadhyovamana* was maintained throughout treatment and follow-up without significant relapse or further deterioration.

INVESTIGATION

Absolute Eosinophil Count.

Differential Count.

ESR.

RESULTS

The combined effect of *Sadhyovamana*, *Gudadeepyaka*, and *Nishottamadi Kashaya* in the management of *Sheetapitta* vis-à-vis Urticaria was evaluated using various assessment parameters. Data were collected from the subjects based on UAS criteria and symptom scoring before intervention, after *Sadhyovamana* Karma, after completion of the intervention, and after follow-up. The obtained results were statistically analyzed using the Wilcoxon matched-pairs test.

Results on Urticaria Activity Score

Among the 31 subjects, UAS severity showed a marked shift towards lower grades following intervention. After *Sadhyovamana*, 41.93% of subjects attained grade 0 severity, with further reduction in higher severity grades after completion of treatment and during follow-up. Wilcoxon matched-pairs analysis demonstrated a highly significant reduction in UAS from a baseline median of 5.1 to 2.4 on Day 3 (52.53% reduction, $p = 0.0001$), which was sustained on Day 31 (61.39% reduction, $p =$

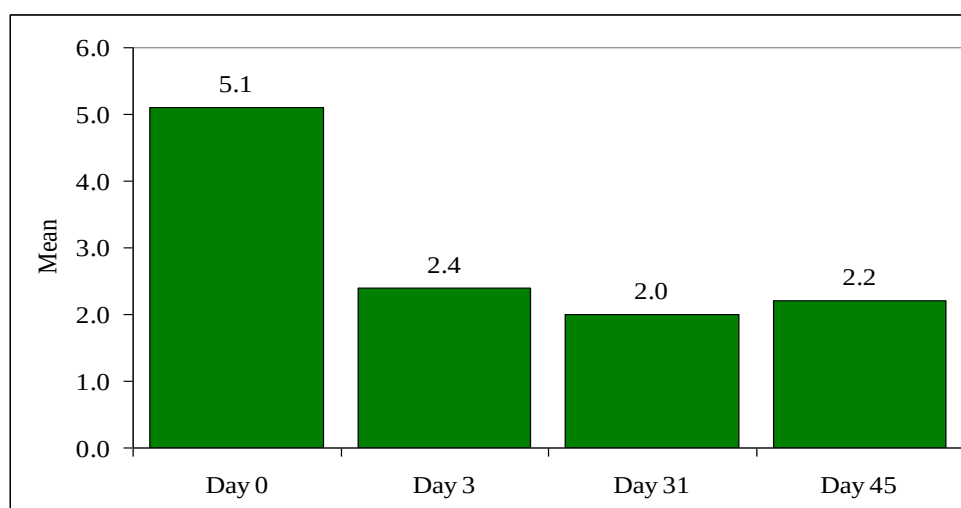


Illustration No. 1: Showing the Mean scores of the Results on UAS from baseline to follow-up.

Results on *Varati Dmshtavat Shotha*

All 31 (100%) subjects presented with *Varati Damshtavat Shotha*. Following *Sadhyovamana*, 48.38% became symptom-free, with a marked reduction in severe and moderate grades. After completion of treatment, no subjects had severe symptoms, while 32.25% were symptom-free; during follow-up, 25.80% remained symptom-free. Wilcoxon matched-pairs analysis demonstrated a highly significant reduction in symptom scores from a baseline median of 2.4 to 1.1 on Day 3 (53.42% reduction, $p = 0.0001$), which was sustained on

Day 31 (56.16% reduction, $p = 0.0001$) and Day 45 (53.42% reduction, $p = 0.0001$). However, comparisons between subsequent assessment points were statistically insignificant ($p > 0.05$), indicating that the initial improvement achieved by *Sadhyovamana* was maintained throughout treatment and follow-up without significant further improvement or deterioration.

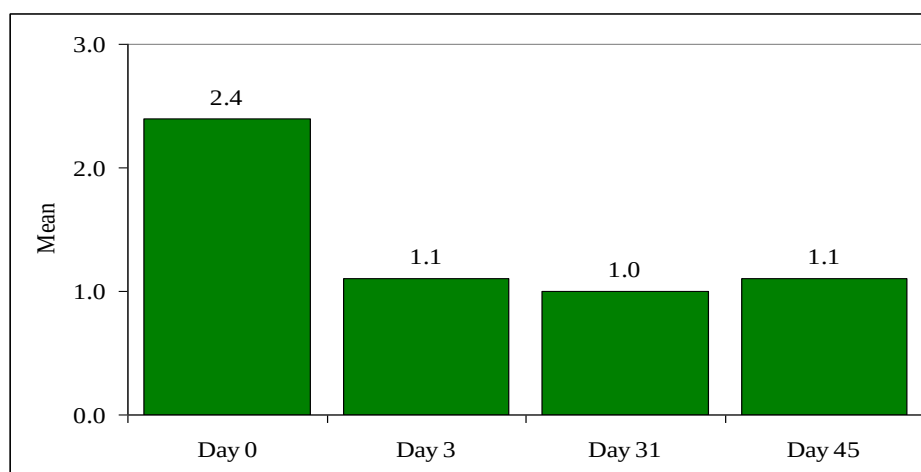


Illustration No. 2: Showing the Mean scores of the Results on *Varati Dmshtavat Shotha* from baseline to follow-up.

Results on *Kandu*

All 31 (100%) subjects presented with *Kandu*. Following *Sadhyovamana*, 48.38% became symptom-free, with a marked reduction in severe and moderate grades. After completion of treatment, 41.93% were symptom-free, while 32.25% remained symptom-free during follow-up. Wilcoxon matched-pairs analysis demonstrated a highly significant reduction in *Kandu* scores from a baseline median of 2.7 to 1.3 on Day 3 (50.60% reduction, $p = 0.0001$), which was sustained on Day 31 (63.86% reduction, $p = 0.0001$) and Day 45 (57.83% reduction, $p = 0.0001$). Comparisons between subsequent assessment

points were statistically insignificant ($p > 0.05$), indicating that the initial improvement achieved by *Sadhyovamana* was maintained throughout treatment and follow-up, without significant further improvement or deterioration.

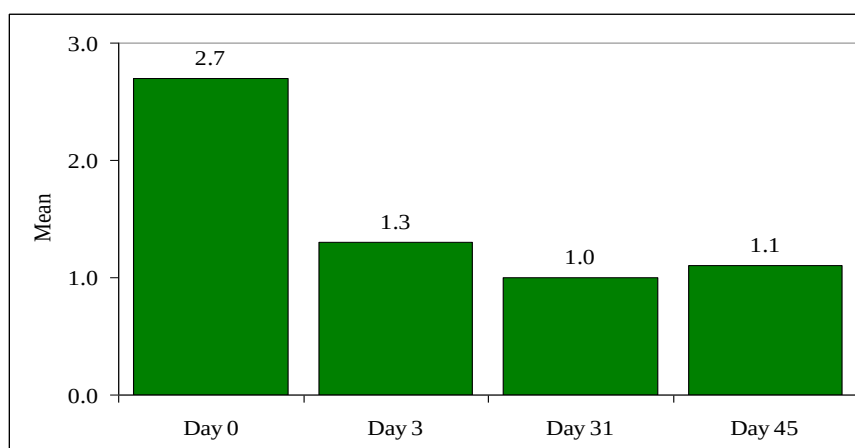


Illustration No. 3: Showing the Mean scores of the Results on Kandu from baseline to follow-up.

Results on Toda

Only 7 (22.58%) subjects presented with *Toda*. Following *Sadhyovamana*, 57.14% became symptom-free, with complete disappearance of severe symptoms. This improvement was maintained after completion of treatment and during follow-up, with 57.14% and 42.85% remaining symptom-free, respectively. Wilcoxon matched-pairs analysis showed a significant reduction in *Toda* scores from a baseline median of 0.6 to 0.2 on Day 3 (72.22% reduction, $p = 0.0180$), which remained

significant on Day 31 (77.78% reduction, $p = 0.0117$) and Day 45 (72.22% reduction, $p = 0.0117$). However, all post-baseline comparisons were statistically insignificant ($p > 0.05$), indicating no significant further change after Day 3. The median score remained 0.0 throughout, suggesting that most subjects had minimal or no *Toda* at baseline and that the observed improvement was mainly reflected in reduced mean scores and IQR.

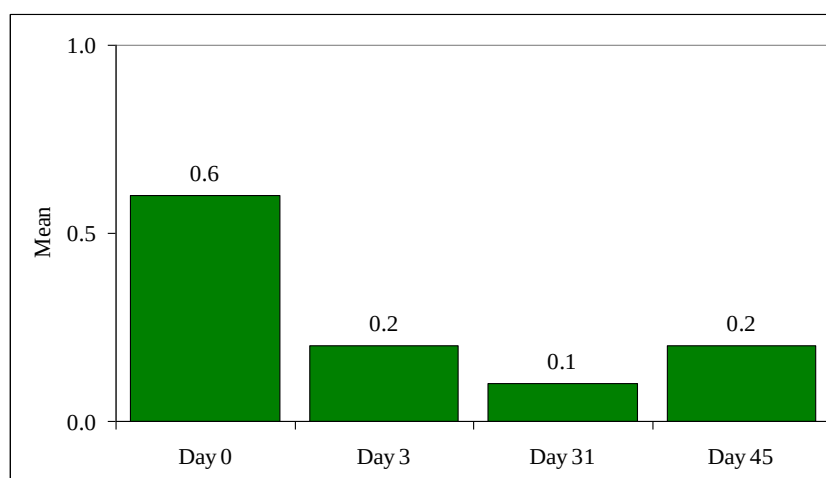


Illustration No. 4: Showing the Mean scores of the Results on Kandu from baseline to follow-up.

Results on Daha

Only 13 (41.93%) subjects presented with *Daha*. Following *Sadhyovamana*, 84.46% became symptom-free, with complete resolution of moderate severity. This improvement was maintained after completion of treatment and during follow-up, with 76.92% and 69.23% remaining symptom-free, respectively. Wilcoxon matched-pairs analysis showed a significant reduction in *Daha* scores by Day 3 (91.30% reduction, $p = 0.0022$), which remained significant on Day 31 (82.61% reduction, $p = 0.0022$) and Day 45 (78.26% reduction, $p = 0.0022$). However, comparisons between subsequent assessment points were statistically insignificant ($p > 0.05$), indicating that the improvement achieved by Day

3 was sustained without significant further change. The median score remained 0.0 throughout, suggesting minimal to no *Daha* in most subjects at baseline; the significant improvement was reflected mainly in reduced mean scores and IQR.

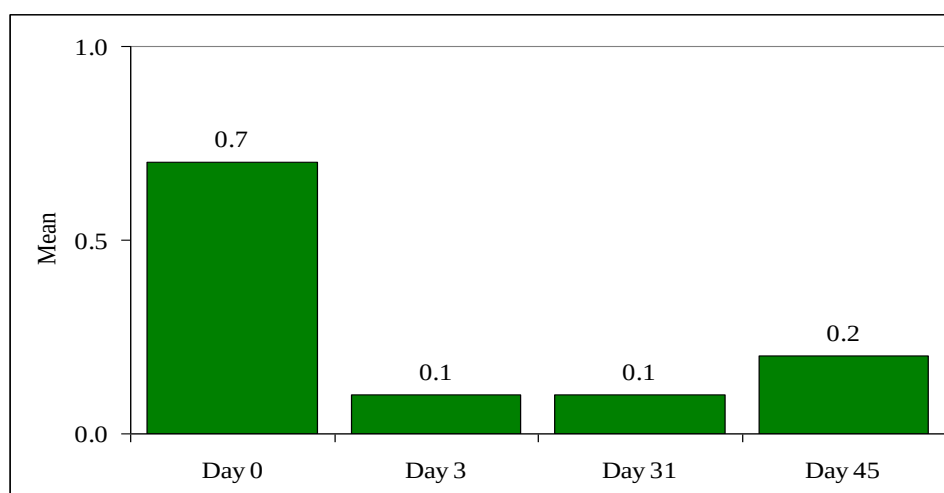


Illustration No. 5: Showing the Mean scores of the Results on *Daha* from baseline to follow-up.

Results on *Chardi*

Only 3 (9.6%) subjects presented with *Chardi*, all with mild severity. Following *Sadhyovamana*, all 3 (100%) became symptom-free, and this improvement was maintained throughout treatment and follow-up. The mean *Chardi* score reduced from 0.1 at baseline to 0.0 by Day 3, representing a 100% reduction; however, the

change was not statistically significant ($p = 0.1088$), as the baseline median and IQR were already 0.0. No further changes were observed on Day 31 or Day 45, indicating complete and sustained resolution of *Chardi* without significant additional improvement.

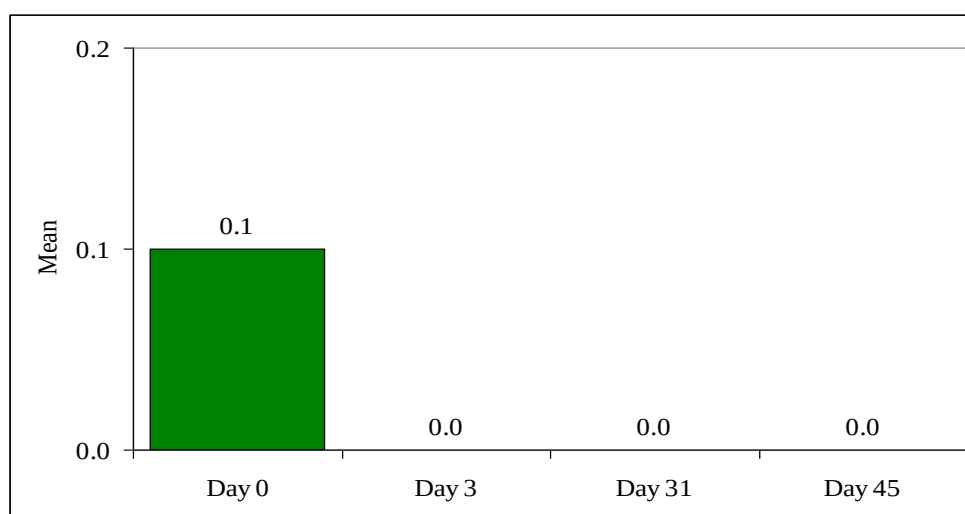


Illustration No. 6: Showing the Mean scores of the Results on *Chardi* from baseline to follow-up.

Results on *Jwara*

Only 6 (19.35%) subjects presented with *Jwara*, all with mild severity. Following *Sadhyovamana*, all 6 (100%) became symptom-free. This improvement was maintained in most subjects, with 66.66% remaining symptom-free after treatment and during follow-up. Wilcoxon matched-pairs analysis showed a significant reduction in the mean *Jwara* score from 0.2 at baseline to 0.0 on Day 3 (100% reduction, $p = 0.0277$). On Days 31 and 45, the mean score was 0.1, representing a 66.67% reduction, but the changes were not statistically significant ($p = 0.0679$). The median and IQR remained 0.0 throughout, indicating minimal symptom burden in most subjects. Overall, *Jwara* showed rapid improvement by Day 3, with mild persistence or

recurrence in a few subjects during subsequent assessments.

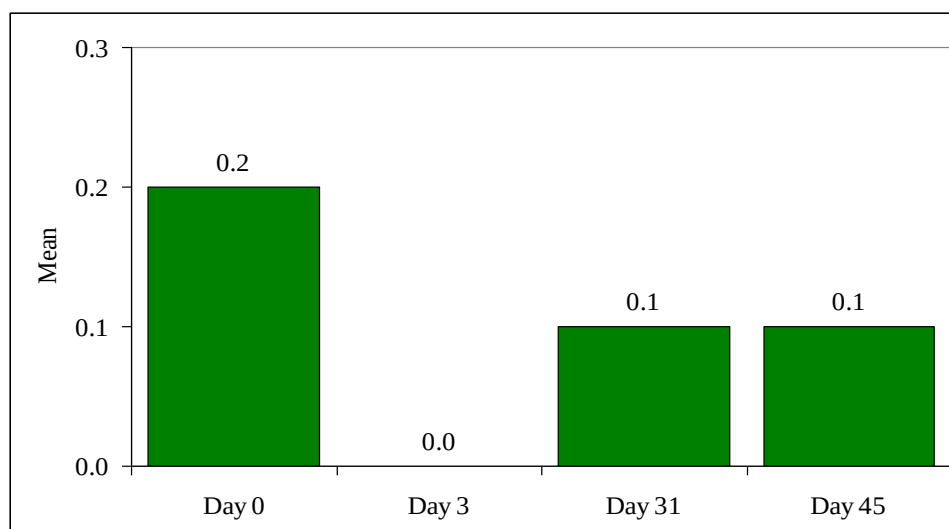


Illustration No. 7: Showing the Mean scores of the Results on Jwara from baseline to follow-up.

Results on Frequency of Attacks

Among the 31 subjects, urticaria attacks were initially daily in 58.06%, on alternate days in 32.25%, and weekly in 9.67%. Following *Sadhyovamana*, 41.93% became attack-free. After completion of treatment, 35.48% remained attack-free, while during follow-up, 29.03% had no attacks, with most subjects experiencing attacks only once weekly. Wilcoxon matched-pairs analysis demonstrated a significant reduction in attack frequency from baseline median 3.0 to 2.0 on Day 3 (40.26% reduction, $p = 0.0004$), 1.0 on Day 31 (64.94% reduction, $p = 0.0001$), and 1.0 on Day 45 (66.23% reduction, $p = 0.0001$). Significant improvement

continued from Day 3 to Day 31 ($p = 0.0177$) and Day 45 ($p = 0.0072$), while no significant change occurred between Day 31 and Day 45 ($p = 0.7353$), indicating progressive improvement followed by stabilization.

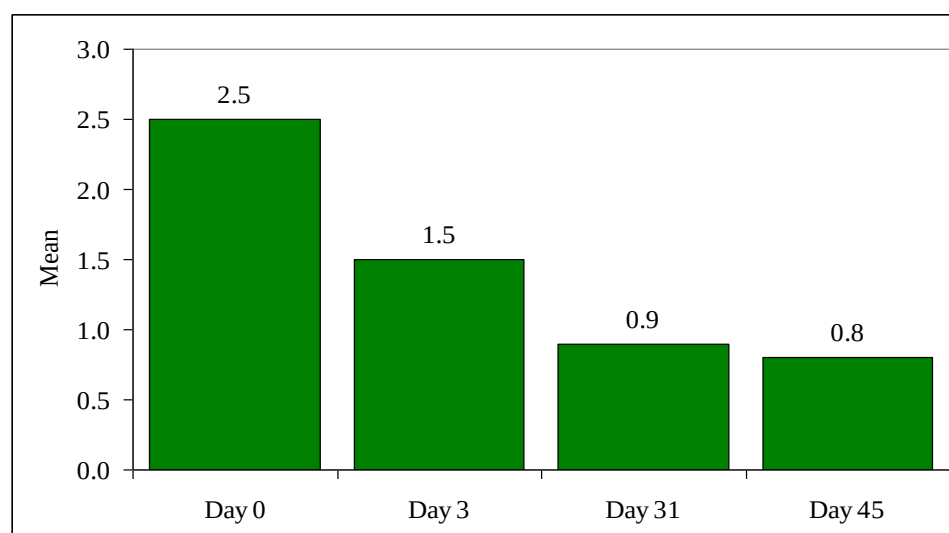


Illustration No. 8: Showing the Mean scores of the Results on Frequency of Attacks from baseline to follow-up.

Overall Clinical Response across Assessment Days

Mean scores of the major clinical parameters from baseline to follow-up.

Day	UAS	Varati Dmshtavat Shotha	Kandu	Daha	Toda	Chardi	Jwara	Frequency of attack
Day 0	5.1	2.4	2.7	0.7	0.6	0.1	0.2	2.5
Day 3	2.4	1.1	1.3	0.1	0.2	0	0	1.5
Day 31	2	1	1	0.1	0.1	0	0.1	0.9
Day 45	2.2	1.1	1.1	0.2	0.2	0	0.1	0.8

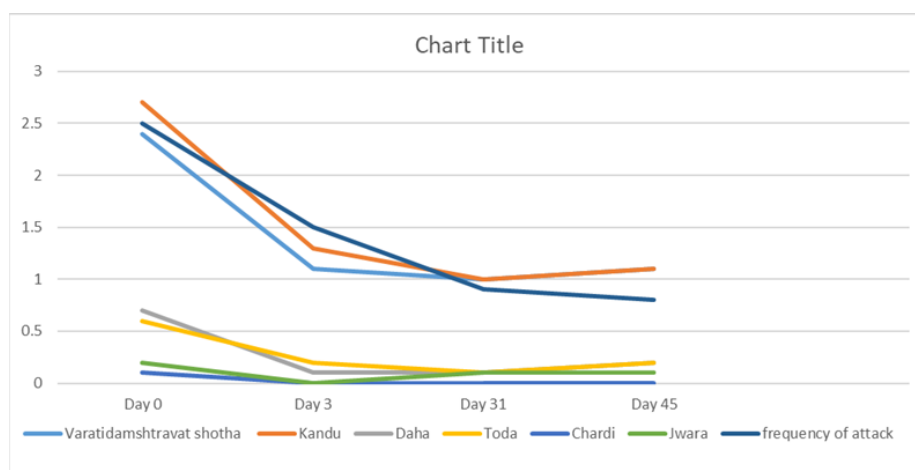


Illustration No. 2- Showing Mean scores of the major clinical parameters from baseline to follow-up.

DISCUSSION

Discussion has been done under the following headings

Discussion on Review of Literature

Discussion on Materials.

Discussion on Results

Discussion on Review of Literature

Sheetapitta is described in Ayurveda as a **Tridoshaja Vyadhi**, predominantly involving Vata and Kapha, with Rakta and Pitta association and primary involvement of Twak, Rasa, and Rakta. Its clinical features closely resemble urticaria, particularly in the sudden appearance of wheals, pruritus, burning, and recurrent nature. The condition is attributed to various **Nidanas**, including cold exposure, dietary incompatibilities, excessive intake of Amla, Lavana and Katu Rasa, certain animal foods and dairy products, suppression of natural urges, disturbed sleep, and psychological stress. From a contemporary perspective, these factors may act through mast-cell activation, histamine release, immune dysregulation, and neuroendocrine mechanisms. The **Samprapti** involves Tridosha Prakopa, Agnimandya, Ama formation, and subsequent dissemination through Rasavaha and Raktavaha Srotas, with localization in Twak. Vata, particularly Vyana Vayu, contributes to the rapid onset and migration of lesions, while Pitta produces erythema and Daha, and Kapha contributes to Kandu and Shotha. Rasa and Rakta are considered the principal Dushyas, with Rasavaha and Raktavaha Srotas being predominantly affected. Ama and Srotorodha further facilitate the persistence and recurrence of the disease. The classical symptom **Varatidamshtavat Shotha** can be correlated with histamine-mediated dermal edema, while Kandu results from stimulation of cutaneous sensory nerves. Daha and Toda may be explained by vascular and neurogenic inflammatory responses, whereas Chardi and Jwara may reflect systemic mediator and cytokine involvement. Thus, the Ayurvedic concepts of Dosha-Dushya interaction, Agnimandya, Ama, and Srotodushti provide a comprehensive framework for understanding the multifactorial pathogenesis of urticaria.

Discussion on Materials

The combined intervention of Sadhyovamana, Gudadeepyaka Churna, and Nishottamadi Kashaya may act through both Shodhana and Shamana mechanisms in Sheetapitta.

Sadhyovamana- It facilitates the expulsion of Utklishta Kapha and associated Pitta from the Amashaya, thereby producing Samprapti Vighatana and reducing the clinical manifestations of the disease.

Probable Mode of Action of Sadhyovamana

The mode of action of Sadhyovamana is fundamentally similar to classical Vamana Karma. According to Acharya Charaka, Vamana Dravyas possessing Ushna, Tikshna, Sukshma, Vyavayi, and Vikasi properties liquefy and dislodge vitiated Doshas from the Srotas and facilitate their movement towards the Amashaya, where they are expelled through the upward action of Udana Vayu.^[8] In Sadhyovamana, as the vitiated Doshas are already accumulated in the Koshta, the process facilitates their prompt elimination. The Tikta-Katu Rasa, Laghu-Ruksha Guna, Ushna Virya, and Katu Vipaka of the Vamana Dravyas, along with the large quantity of Vamanopaga Dravyas, stimulate gastric distension and sensory receptors, activating the vomiting centre through vagal and sympathetic pathways and producing coordinated emesis. In Sheetapitta, this primarily facilitates the expulsion of aggravated Kapha and associated Pitta from the Amashaya, thereby producing Samprapti Vighatana and reducing Kandu, Daha, Toda, and Varatidamshtavat Shotha.^[9]

Gudadeepyaka Churna- Gudadeepyaka Churna, comprising Guda and Deepyaka (Ajamoda), acts through both Ayurvedic and pharmacological mechanisms in Sheetapitta. Guda, with Madhura Rasa, Snigdha Guna, and Vata-Pittahara and Raktaprasadaka properties, helps restore Dosha balance and pacify Rakta-Pitta. Ajamoda, owing to its Deepana, Pachana, Kapha-Vatahara, and Vatanulomana properties, corrects Agnimandya and Ama. Its bioactive constituents, particularly umbelliferone,^[10] luteolin,^[11] chrysoeriol,

and volatile oils, exhibit anti-inflammatory, antioxidant, antihistaminic, and antiallergic activities. These constituents may inhibit mast-cell degranulation and histamine release, thereby reducing wheal formation, Kandu, Daha, and other manifestations of urticaria. Thus, Gudadeepyaka Churna may contribute to Samprapti Vighatana through correction of Agni, Dosha Shamana, and modulation of allergic inflammation.

Nishottamadi Kashaya -Nishottamadi Kashaya, predominantly comprising Tikta-Katu Rasa and possessing Kapha-Pitta Shamaka properties, acts by alleviating Dosha vitiation and supporting Rakta Prasadana in Sheetapitta. Its constituents such as Haridra, Nimba, Patola, Tikta, Vacha, Manjishta, and Yashtimadhu exhibit anti-inflammatory, antioxidant, antiallergic, antihistaminic, and immunomodulatory activities. These actions may inhibit mast-cell degranulation, histamine release, and inflammatory mediator production, thereby reducing wheal formation, Kandu, Daha, and erythema.

Discussion on Results

In the present study, **Sadhyovamana produced significant overall improvement in Sheetapitta**, with the maximum response observed by Day 3 and sustained through Day 45. Significant reductions were observed in UAS, Varati Damshtavat Shotha, Kandu, Toda, Daha, and total symptom scores ($p = 0.0001$), while Chardi and Jwara, being infrequent and mild at baseline, showed early resolution with occasional minimal recurrence. The frequency of urticarial attacks demonstrated progressive and significant improvement up to Day 31, indicating a gradual reduction in disease recurrence. Overall improvement was **70.04% on Day 3, 71.68% on Day 31, and 68.95% on Day 45**, suggesting a sustained therapeutic effect with a plateau after the initial response. The rapid improvement may be attributed to the elimination of vitiated Kapha and Pitta through Sadhyovamana, resulting in early reduction of inflammatory and hypersensitivity manifestations, while the sustained response may reflect stabilization of Dosha balance and reduction in disease recurrence. Minor fluctuations during follow-up may be related to residual Dosha involvement or continued exposure to triggering factors.

CONCLUSION

This open-label single-arm study suggests that the combined use of Sadhyovamana, Gudadeepyaka Churna, and Nishottamadi Kashaya is a safe and effective approach for managing Sheetapitta vis-à-vis urticaria. Among 33 enrolled subjects, 31 completed the study, with clinical improvement increasing from 70.04% after Sadhyovamana to 71.68% after Shamana therapy and remaining sustained at 68.95% during follow-up. The significant early improvement indicates a major therapeutic contribution of Sadhyovamana, while subsequent Shamana therapies helped maintain symptom relief. No major adverse events were observed,

supporting the treatment's safety and tolerability; however, larger randomized controlled studies with longer follow-up are needed to confirm these findings.

ACKNOWLEDGEMENT

The authors sincerely thank all the physicians and consultants who referred cases for this study. We extend our heartfelt gratitude and respect to all the participants; whose trust and cooperation were indispensable to the successful completion of this research. We also deeply appreciate our colleagues for their insightful feedback and constructive discussions, which greatly contributed to enhancing the quality of this work.

Financial support and sponsorship-Nil.

Conflicts of interest -Authors have no conflict of interest to declare.

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