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A COMPARATIVE CLINICAL STUDY ON THE MANAGEMENT OF SHEETAPITTA WITH SPECIAL REFERENCE TO URTICARIA BY THE ORAL USE OF ADRAKA KHANDA WITH OR WITHOUT NIMBADI LEPA

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ABSTRACT

Background: Sheetapitta is described in Ayurveda as a disorder characterized by recurrent wheal-like eruptions, itching, pricking sensation, burning and occasionally fever. Its clinical manifestations resemble urticaria, a dermatological condition involving transient wheals and pruritus. Ayurvedic management may include internal formulations and external applications selected according to the clinical presentation and traditional therapeutic principles. **Aim:** To evaluate and compare the clinical efficacy of oral Adraka Khanda alone and oral Adraka Khanda combined with externally applied Nimbadi Lepa in patients with Sheetapitta with special reference to urticaria. **Materials and Methods:** An interventional, prospective, randomized, open-label comparative clinical study was conducted at the Institute of Postgraduate Ayurvedic Education and Research at Shyamadas Vaidya Shastra Pith Hospital, Kolkata. Sixty patients completed the study and were divided into two groups of 30 each. Group A received Adraka Khanda 10 g orally twice daily after meals for 45 days. Group B received the same oral treatment with Nimbadi Lepa applied externally twice daily for 45 days. Clinical assessment included Mandala, Kandu, Toda, Vidaha and Jwara. Laboratory assessment included WBC count, eosinophil level and serum IgE. **Results:** Both groups demonstrated statistically significant within-group improvement in subjective parameters (reported $p<0.001$). Group A showed 66.27%, 63.90%, 47.89%, 57.20% and 55.10% relief in Mandala, Kandu, Toda, Vidaha and Jwara, respectively. Corresponding improvements in Group B were 76.40%, 70.00%, 78.08%, 82.14% and 66.67%. Between-group differences were statistically significant for Toda, Vidaha and Jwara. Laboratory parameters decreased in both groups, but the differences between groups were not statistically significant. **Conclusion:** Both treatment regimens were associated with clinical improvement during the study period. The addition of Nimbadi Lepa was associated with greater improvement in selected subjective symptoms. Further controlled studies are necessary to establish treatment-specific efficacy and long-term safety.

KEYWORDS: Sheetapitta; Urticaria; Adraka Khanda; Nimbadi Lepa; Ayurveda; Kayachikitsa; Comparative Clinical Study.

INTRODUCTION

Skin diseases constitute a significant group of clinical conditions encountered in routine medical practice. They may affect physical comfort, appearance, emotional well-being, sleep and daily activities. Urticaria is characterized by the sudden appearance of erythematous, edematous wheals accompanied by itching. Individual wheals are generally transient, although recurrent episodes may cause considerable discomfort and impair quality of life. The clinical presentation varies according

to disease duration, precipitating factors and individual susceptibility. Dermatological literature recognizes urticaria as a heterogeneous condition requiring appropriate clinical evaluation and classification.[1]

Ayurveda approaches disease through the concepts of Dosha, Dhatu, Mala, Agni and the relationship between the individual and the surrounding environment. Classical descriptions emphasize the importance of maintaining physiological equilibrium through appropriate dietary habits, lifestyle practices and therapeutic measures. Disturbances in these factors are considered relevant to the development of various diseases, including those affecting the skin. Charaka Samhita provides a classical foundation for understanding Dosha involvement and its relevance to disease manifestations.[2]

Sheetapitta is described in Ayurvedic literature as a disorder involving Vata and Kapha along with Pitta. Madhavakara describes characteristic manifestations such as Mandala, Kandu, Toda and Vidaha. These symptoms show considerable similarity to the clinical presentation of urticaria. Nevertheless, the two conditions originate from different diagnostic systems and should not be regarded as completely interchangeable.[3]

The classical understanding of Sheetapitta includes the interaction of aggravated Dosha and their effects on the skin. The condition may present with raised lesions, itching, pricking pain, burning sensation and occasionally systemic complaints. The clinical features are used to evaluate disease severity and guide treatment selection. Ayurvedic texts also describe related conditions such as Udarda and Kotha, emphasizing the importance of clinical differentiation.[4]

Chakradatta describes therapeutic approaches for Sheetapitta and related disorders. The classical treatment principles emphasize the selection of medicines according to the predominant clinical manifestations and the Ayurvedic understanding of Dosha involvement. These descriptions provide a traditional foundation for investigating different internal and external formulations.[5]

Bhavaprakasha further discusses Sheetapitta, Udarda and Kotha and their management. Traditional therapeutic principles include consideration of causative factors, dietary practices and medicines selected according to their Rasa, Guna, Virya, Vipaka and Karma. The therapeutic rationale is based on addressing the disturbed physiological balance described in Ayurvedic theory.[6]

Yogaratnakara also contains descriptions of Sheetapitta-related conditions and their management. These classical sources collectively provide the theoretical background for studying Ayurvedic formulations intended to alleviate itching, burning and other cutaneous symptoms.[7]

Vangasena Samhita describes therapeutic approaches for several disorders, including Sheetapitta, Udarda and Kotha. Its inclusion in the traditional literature demonstrates the longstanding interest in the management of recurrent skin manifestations through different therapeutic measures.[8]

From the perspective of contemporary medicine, urticaria may be classified as acute or chronic according to symptom duration. Chronic urticaria is generally characterized by recurrent wheals, angioedema or both for more than six weeks. International clinical guidelines recommend careful assessment of disease activity, identification of relevant triggers and appropriate pharmacological treatment. Second-generation H1-antihistamines constitute first-line treatment, with additional options for patients whose symptoms remain inadequately controlled.[9]

The clinical manifestations of urticaria may fluctuate over time. Individual wheals can appear and disappear rapidly, while the overall disease may persist or recur. Historical clinical observations have documented the variable course of urticaria and angioedema, emphasizing the importance of evaluating disease activity over an appropriate period.[10]

The present clinical study investigated two Ayurvedic treatment approaches. Adraka Khanda was selected as the internal formulation. The preparation contained Adraka, Go-Ghrita, Go-Dugdha, Sharkara and additional Prakshepa Dravya. Its selection was based on the traditional pharmaceutical and therapeutic rationale described in the dissertation. Classical Ayurvedic formulations and their applications are discussed in Bhaisajya Ratnavali.[11]

Adraka is widely described in Ayurvedic medicinal literature and is traditionally associated with Deepana, Pachana and other therapeutic properties. These descriptions provide a theoretical basis for its selection in internal formulations. However, traditional therapeutic indications alone do not establish clinical efficacy against urticarial.[12]

Nimbadi Lepa was selected as an external preparation containing Nimba and Amalaki. Nimba is traditionally associated with Kandughna, Kushtaghna and Pitta-Kapha Shamaka properties. Amalaki is described in relation to Rasayana and Pitta-related therapeutic concepts. The combination was selected for investigation as a topical adjunct to oral Adraka Khanda.[13]

Ayurvedic medicinal-plant literature describes the traditional properties and applications of Nimba and Amalaki. These sources provide background information on the selected ingredients, although the effectiveness of

the combined topical preparation must be established through clinical investigation.[14]

The use of internal and external therapeutic measures reflects a traditional Ayurvedic approach in which systemic and local interventions may be combined. Nevertheless, the additional clinical benefit of external Nimbadi Lepa requires comparative assessment.

The present study was therefore undertaken to compare the effects of oral Adraka Khanda alone with oral Adraka Khanda combined with Nimbadi Lepa in patients diagnosed with Sheetapitta.

AIM

To evaluate and compare the clinical efficacy of Adraka Khanda alone and Adraka Khanda combined with Nimbadi Lepa in the management of Sheetapitta with special reference to urticaria.

OBJECTIVES

The objectives were to evaluate changes in Mandala, Kandu, Toda, Vidaha and Jwara; assess changes in WBC count, eosinophil level and serum IgE; compare treatment responses between the two groups; and document adverse effects or complications during the study period.

MATERIALS AND METHODS

STUDY DESIGN AND SETTING

The present study was an interventional, prospective, randomized, open-label comparative clinical trial conducted in the Department of Kayachikitsa at the Institute of Postgraduate Ayurvedic Education and Research at Shyamadas Vaidya Shastra Pith Hospital, Kolkata.

The dissertation describes simple randomization, although the reviewed sections do not provide sufficient information to independently verify the sequence-generation and allocation-concealment procedures.

Study population

Approximately 65 patients were registered for the study. Sixty patients completed the clinical assessment and were divided into two groups of 30 participants each.

Patients were selected according to the clinical eligibility criteria described in the dissertation.

INCLUSION CRITERIA

Patients aged 20–70 years of either sex were considered eligible when they had clinical manifestations consistent with chronic Sheetapitta or urticaria, including recurrent wheals, itching and burning sensation.

The study included patients with a history of recurrent symptoms for more than six weeks who were willing to participate and provide informed consent.

EXCLUSION CRITERIA

Patients with significant systemic illnesses, including uncontrolled diabetes mellitus, uncontrolled hypertension, active tuberculosis, malignancy, chronic renal failure and chronic liver disease, were excluded.

Pregnant women, patient's dependent on long-term corticosteroid therapy and individuals unwilling to participate were also excluded.

Ethical approval

The study was approved by the Institutional Ethics Committee under reference number **SVP/IEC/846/2024**, dated 29 May 2024.

Informed consent was obtained according to the dissertation protocol.

PREPARATION OF TRIAL FORMULATIONS

Adraka Khanda: The formulation contained Adraka, Go-Ghrita, Go-Dugdha, Sharkara and additional Prakshepa Dravya. It was prepared in the institutional apothecary according to the pharmaceutical procedure described in the dissertation. Classical Ayurvedic pharmaceutical literature discusses the preparation and administration of medicinal formulations, including relevant dosage forms and processing methods.[15]

Nimbadi Lepa: The topical preparation was prepared using the powders of Nimba and Amalaki. It was intended for external application to affected skin areas.

INTERVENTION PROTOCOL

Group	Treatment	Duration
Group A (n=30)	Adraka Khanda 10 g orally twice daily after meals with lukewarm water	45 days
Group B (n=30)	Adraka Khanda 10 g orally twice daily after meals with lukewarm water, plus Nimbadi Lepa applied externally twice daily approximately 30 minutes before bathing	45 days

ASSESSMENT PARAMETERS

The subjective parameters included Mandala, Kandu, Toda, Vidaha and Jwara. Each symptom was assessed according to the grading system described in the dissertation.

Objective parameters included total WBC count, eosinophil level and serum IgE. Laboratory investigations were performed before and after the treatment period.

Clinical assessment of urticaria involves documenting symptom severity and disease activity. Standard

dermatological literature describes the importance of evaluating wheals, itching and associated manifestations during clinical follow-up.[16]

OVERALL RESPONSE ASSESSMENT

The dissertation classified overall clinical response according to percentage improvement.

- Complete remission: 100% relief.
- Marked improvement: at least 75% but less than 100% relief.
- Moderate improvement: at least 50% but less than 75% relief.
- Mild improvement: at least 25% but less than 50% relief.
- Insignificant improvement: less than 25% relief.

Statistical analysis

The dissertation reported before-treatment and after-treatment comparisons and between-group statistical analyses. Results were expressed as mean scores, percentage improvement and p-values.

A p-value below 0.05 was considered statistically significant. Appropriate statistical test selection depends on study design, data distribution and measurement scale, as described in standard medical biostatistics literature.[17]

The specific tests used for each comparison should be confirmed from the original statistical analysis before submission.

Reporting considerations

The dissertation described the study as randomized and open-label. Transparent reporting of allocation procedures, participant flow, outcome measures and statistical methods is important for the interpretation of comparative clinical trials.[18]

For herbal interventions, accurate documentation of botanical identity, pharmaceutical preparation, dosage and intervention reproducibility is particularly important.[19]

The clinical outcomes reported in this article were extracted from the original dissertation and its associated clinical assessment tables. The dissertation serves as the primary source of the study data.[20]

RESULTS

STUDY COMPLETION

Sixty patients completed the study, with 30 participants in Group A and 30 in Group B.

Both groups underwent clinical assessment before and after the 45-day intervention.

CHANGES IN SUBJECTIVE PARAMETERS

Table 1: Mean subjective scores before and after treatment.

Parameter	Group A BT	Group A AT	Group B BT	Group B AT
Mandala	2.77	0.93	2.67	0.63
Kandu	2.27	0.87	2.40	0.70
Toda	2.43	1.23	2.60	0.57
Vidaha	2.50	1.07	2.80	0.50
Jwara	1.27	0.63	1.57	0.47

BT: Before treatment; AT: After treatment.

Both groups demonstrated improvement in all five subjective parameters. The dissertation reported statistically significant within-group changes ($p<0.001$).

COMPARATIVE PERCENTAGE RELIEF

Table 2: Percentage improvement in subjective symptoms.

Parameter	Group A (%)	Group B (%)	Between-group significance
Mandala	66.27	76.40	Not significant
Kandu	63.90	70.00	Not significant
Toda	47.89	78.08	$p<0.001$
Vidaha	57.20	82.14	$p<0.001$
Jwara	55.10	66.67	$p<0.05$

Group B demonstrated greater numerical improvement in all five subjective parameters.

The between-group differences were statistically significant for Toda, Vidaha and Jwara, whereas those for Mandala and Kandu were not statistically significant.

MANDALA

Mandala represents wheal-like cutaneous lesions. Group A demonstrated 66.27% improvement, whereas Group B demonstrated 76.40% improvement.

Although the combined-treatment group showed greater numerical relief, the between-group difference was not statistically significant.

KANDU

Kandu represents itching, one of the principal symptoms of Sheetapitta.

Group A demonstrated 63.90% improvement, while Group B demonstrated 70.00% improvement.

The numerical difference favored Group B, but statistical significance was not established.

TODA

Toda represents a pricking sensation.

Group A showed 47.89% improvement, whereas Group B showed 78.08% improvement.

The difference between groups was statistically significant ($p<0.001$), indicating greater improvement in the combined-treatment group.

VIDAHA

Vidaha represents burning sensation.

Group A demonstrated 57.20% relief, while Group B demonstrated 82.14% relief.

The between-group difference was statistically significant ($p<0.001$).

Jwara

Group A demonstrated 55.10% improvement in Jwara, whereas Group B demonstrated 66.67% improvement.

The between-group difference was reported as statistically significant ($p<0.05$).

OBJECTIVE PARAMETERS

Table 3: Mean laboratory values before and after treatment.

Parameter	Group A BT	Group A AT	Group B BT	Group B AT
WBC count	7746.33	7350.00	7903.67	7490.00
Eosinophil level	12.97	5.97	14.23	6.47
Serum IgE	1140.70	543.51	1340.39	653.24

Units and laboratory reference ranges should be verified against the original records.

Both groups demonstrated reductions in the recorded laboratory parameters.

The dissertation reported percentage reductions of approximately 5.12%, 53.97% and 52.00% for WBC count, eosinophil level and serum IgE in Group A.

Corresponding reductions in Group B were approximately 5.23%, 54.57% and 48.00%.

The reported between-group differences were not statistically significant.

OVERALL CLINICAL IMPROVEMENT

Table 4: Distribution of overall treatment response.

Response category	Group A	Group B
Mild improvement	3 (10.00%)	2 (6.67%)
Moderate improvement	21 (70.00%)	22 (73.33%)
Marked improvement	6 (20.00%)	5 (16.67%)
Complete cure	0	1 (3.33%)
No improvement	0	0
Total	30	30

The majority of patients in both groups demonstrated moderate improvement.

One patient in Group B was classified as completely cured according to the dissertation's response criteria.

No significant adverse effects or complications were reported during the study period.

DISCUSSION

The present comparative clinical study evaluated the effects of Adraka Khanda alone and Adraka Khanda combined with Nimbadi Lepa in patients diagnosed with Sheetapitta.

Both groups demonstrated improvement in the recorded subjective clinical parameters during the 45-day intervention period. The combined-treatment group showed greater numerical improvement in all five subjective parameters, with statistically significant between-group differences for Toda, Vidaha and Jwara.

AYURVEDIC INTERPRETATION

According to the traditional Ayurvedic understanding described in the dissertation, Sheetapitta involves disturbances of Vata, Pitta and Kapha. The manifestations of itching, pricking pain, burning and wheal-like lesions are interpreted according to the predominance and interaction of these Dosha.

The treatment rationale involved the use of an internal formulation together with an external application. Adraka Khanda was selected as the oral intervention,

while Nimbadi Lepa was investigated as an additional topical treatment.

Adraka is traditionally associated with Deepana and Pachana properties. Within the Ayurvedic framework, these properties are considered relevant to the correction of disturbed digestive and metabolic functions.

Nimba is traditionally described as possessing Kandughna and Kushtaghna properties, while Amalaki is associated with Rasayana and Pitta-related therapeutic concepts.

The dissertation proposed that the combination of internal and external interventions might provide greater symptomatic relief by addressing both systemic and local manifestations.

These explanations represent traditional therapeutic interpretations. The clinical trial did not directly investigate the molecular or biochemical mechanisms responsible for the observed improvement.

EFFECT ON MANDALA

Mandala was one of the principal clinical manifestations assessed during the study.

Group A demonstrated 66.27% improvement, while Group B demonstrated 76.40% improvement.

The numerical advantage observed in Group B suggests that the additional topical intervention may have contributed to relief from wheal-like lesions.

However, the between-group difference was not statistically significant. Therefore, the results do not establish superiority of the combined treatment for Mandala.

EFFECT ON KANDU

Kandu is a prominent and often distressing symptom of Sheetapitta.

The study demonstrated 63.90% improvement in Group A and 70.00% improvement in Group B.

The greater numerical improvement in Group B may be related to the additional topical application. However, the difference was not statistically significant.

The improvement observed in both groups indicates that itching decreased during the treatment period, but the study design does not permit the observed change to be attributed exclusively to the interventions.

EFFECT ON TODA

Toda demonstrated a marked difference between the two treatment groups.

Group A showed 47.89% improvement, whereas Group B showed 78.08% improvement.

The between-group difference was statistically significant.

This finding suggests that the combined intervention was associated with greater improvement in the recorded pricking sensation.

The dissertation interpreted this improvement in relation to the traditional properties of the topical formulation. Nevertheless, the precise mechanism remains unestablished.

EFFECT ON VIDAHA

Vidaha represents burning sensation and may contribute substantially to patient discomfort.

Group A demonstrated 57.20% relief, while Group B demonstrated 82.14% relief.

The between-group difference was statistically significant.

The greater improvement in Group B may indicate an additional symptomatic benefit from Nimbadi Lepa. However, because the study did not include a topical placebo control, nonspecific topical effects and expectation-related influences cannot be excluded.

EFFECT ON JWARA

The study reported improvement in Jwara in both groups. Group A demonstrated 55.10% improvement, whereas Group B demonstrated 66.67% improvement.

The between-group difference was reported as statistically significant.

The interpretation of this finding requires consideration of the baseline severity and frequency of fever among the study participants. The dissertation's aggregate data do not establish whether this parameter represented measured body temperature or a graded clinical symptom in every case.

EFFECT ON LABORATORY PARAMETERS

Both groups demonstrated reductions in WBC count, eosinophil level and serum IgE.

The reductions in eosinophil level and serum IgE were numerically substantial. However, the reported differences between the two treatment groups were not statistically significant.

These observations suggest that laboratory values changed during the study period, but they do not establish that the interventions directly modified the underlying immunological mechanisms of urticaria.

Urticaria involves complex biological processes, and laboratory measurements must be interpreted in the context of clinical presentation, disease classification and other relevant factors.

The absence of significant between-group differences limits any conclusion regarding superior immunological effects of the combined regimen.

OVERALL CLINICAL RESPONSE

The majority of participants in both groups demonstrated moderate improvement.

In Group A, 70.00% of participants showed moderate improvement, 20.00% showed marked improvement and 10.00% showed mild improvement.

In Group B, 73.33% demonstrated moderate improvement, 16.67% demonstrated marked improvement, 6.67% demonstrated mild improvement and 3.33% were classified as completely cured.

The overall response distribution was broadly similar between groups, although Group B included one participant classified as completely cured.

These findings should be interpreted alongside the parameter-specific results rather than used as independent proof of overall superiority.

CLINICAL SIGNIFICANCE

The present study provides preliminary comparative observations concerning two Ayurvedic treatment approaches.

The findings indicate that both regimens were associated with improvement in the recorded symptoms during the 45-day intervention period.

The addition of Nimbadi Lepa was associated with greater improvement in selected parameters, particularly Toda and Vidaha.

However, the study did not include a placebo, topical vehicle control or standard pharmacological comparator. Consequently, the results cannot establish equivalence or superiority to conventional urticaria treatment.

SAFETY OBSERVATIONS

The dissertation reported no significant adverse drug reactions or complications during the study period.

This finding suggests that no major treatment-related problems were documented among the 60 participants during the observation period.

Nevertheless, the small sample size and limited duration do not permit conclusions regarding long-term safety, uncommon adverse effects or safety in populations excluded from the study.

STRENGTHS OF THE STUDY

The study employed a comparative design in which both groups received the same oral formulation.

The addition of Nimbadi Lepa in Group B allowed an exploratory assessment of the potential contribution of topical treatment.

The study also included defined treatment schedules, structured clinical assessments and selected laboratory investigations.

The use of both subjective and objective parameters provided a broader description of the changes observed during treatment.

LIMITATIONS

The study had several limitations.

First, the sample size was relatively small, and the research was conducted at a single institution.

Second, the open-label design may have introduced performance and assessment bias, particularly because several outcomes depended on subjective symptom scoring.

Third, the dissertation does not provide sufficient detail in the reviewed sections to verify allocation concealment or blinded outcome assessment.

Fourth, the trial lacked a placebo group, topical vehicle control and conventional-treatment comparator.

Fifth, the 45-day treatment period was insufficient to determine long-term recurrence, sustained remission or delayed adverse effects.

Finally, the dissertation contains an inconsistency in its combined overall-response summary. The group-wise response counts total 60 participants, whereas one summary passage reports category totals exceeding the stated sample size. The group-wise counts have therefore been retained pending verification against the original master chart.

FUTURE RESEARCH

Future studies should use adequately powered randomized controlled designs with clearly documented randomization procedures.

Blinded assessment and appropriate control groups would improve the reliability of clinical findings.

Validated urticaria outcome instruments should be incorporated to improve reproducibility and facilitate comparison with other studies.

Longer follow-up is required to evaluate recurrence, sustained symptom control and delayed adverse effects.

Further investigations should also address pharmaceutical standardization, formulation stability, botanical authentication and topical tolerability.

CONCLUSION

The present comparative clinical study evaluated oral Adraka Khanda alone and oral Adraka Khanda combined with Nimbadi Lepa in 60 patients diagnosed with Sheetapitta with special reference to urticaria.Both groups demonstrated statistically significant improvement in the recorded subjective symptoms during the 45-day treatment period.Group B showed greater numerical improvement in all five subjective parameters, with statistically significant between-group differences reported for Toda, Vidaha and Jwara.Reductions in WBC count, eosinophil level and serum IgE were observed in both groups, but no statistically significant between-group differences were established for these laboratory parameters.No significant adverse reactions were reported during the study period. However, the sample size and follow-up duration were insufficient to establish comprehensive or long-term safety.The findings suggest that the addition of Nimbadi Lepa may provide further symptomatic benefit in selected manifestations of Sheetapitta. Larger, methodologically rigorous controlled trials are required to confirm these observations.

DECLARATIONS

Ethical approval: The study was conducted according to the institutional ethical requirements described in the thesis.

Clinical trial registration: CTRI/2024/08/072289.

Informed consent: Written informed consent was obtained from participants according to the study documents.

Funding: No external funding was reported in the thesis.

Conflict of interest: No conflict of interest was reported in the thesis.

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