

A RANDOMIZED OPEN-LABEL CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF AMRITADI YOGA IN THE MANAGEMENT OF SHEETAPITTA WITH SPECIAL REFERENCE TO URTICARIA

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Abstract:

Context: Ayurveda focuses on the dynamic integration between the body, mind, and environment. *Sheetapitta* is a skin disorder caused by '*Asatmya Sevana*' (exposure to allergens) and is co-related with Urticaria in modern medicine.

Objective: To evaluate and compare the efficacy of *Amritadi Yoga* (trial drug) against *Haridra Khanda* (controlled drug) in managing *Sheetapitta*.

Methodology: A randomized, open-label, parallel-group clinical study was conducted with 30 subjects (15 per group) for a trial period of 30 days. Group A received *Amritadi Yoga* (Kashaya) and Group B received *Haridra Khanda*.

Results: Both interventions showed significant relief. Group A showed higher efficacy in reducing cardinal symptoms like *Kandu* (itching), *Toda* (pricking pain), and *Mandalotpatti* (wheal formation).

Conclusion: *Amritadi Yoga* is a safe and effective Ayurvedic intervention for managing *Sheetapitta* (Urticaria) at an OPD level.

INTRODUCTION

Ayurveda defines health as the equilibrium of *Dosha*, *Dhatu*, *Agni*, and *Mala*. *Sheetapitta* is characterized by the sudden eruption of itchy wheals on the skin and mucous membranes. It is primarily caused by the vitiation of *Vata* and *Kapha Dosha*, which subsequently mixes with *Pitta*.

Need For Study: Urticaria affects approximately 15-20% of the general population. While modern medicine uses antihistamines, they often require long-term use and may have side effects. Ayurveda provides a permanent management option through drugs that clear micro-channels and balance the *Tridoshas*.

DRUG REVIEW

Group A: Amritadi Yoga (Trial Drug)

- **Ingredients:** *Amrita* (Guduchi), *Haridra*, *Nimba*, and *Dhamasa*.
- **Properties:** These drugs possess *Tikta-Katu Rasa*, *Ushna Veerya*, and *Katu Vipaka*.
- **Action:** They act as *Tridosha Shamaka*, *Raktashodhaka* (blood purifier), and *Kandughna* (anti-pruritic).

Group B: Haridra Khanda (Controlled Drug)

- **Ingredients:** *Haridra*, *Haritaki*, *Trivrit*, *Daruharidra*, *Nagarmotha*, and *Trikatu*.
- **Properties:** Primarily *Pitta-Kapha Hara* with anti-inflammatory and antihistaminic properties.

MATERIALS AND METHODS

Source of Data: 30 patients were selected from the OPD and IPD of JIAR Hospital, Jammu.

Study Design: Randomized, open-label, parallel-group, pre- and post-test clinical study.

- **Sample Size:** 30 subjects (15 per group).
- **Randomization:** Done by chits.
- **Trial Duration:** 45 days (30 days drug trial + 15 days follow-up).

A. INCLUSION CRITERIA

1. Patients of age 20-40 yrs will be taken for study.
2. Patients showing and also with history of classical clinical features like - *Kandu, Toda, Mandalotpati, Daha, Jawar, Chardi.Sheetapitta* (Urticarial rashes).
3. Patients willing for trial.

B. EXCLUSION CRITERIA

1. Patients suffering from any other systemic disorders like HTN, DM, IHD and HIV.
2. Patients is having any malignancy or tumor.
3. History of Angioedema.
4. Other skin diseases like Psoriasis, Eczema.
5. History of active bleeding from rashes.

C. DIAGNOSTIC CRITERIA

1. Total Leukocyte count (TLC)
2. Differential Leukocyte count (DLC)
3. Absolute Eosinophil count (AEC)

D. CRITERIA FOR ASSESSMENT

Assessment will be done before and after the treatment adopting the following parameters:-

SUBJECTIVE CRITERIA

Table No. 1 : Criteria for Assessment

1) **KANDU** –

Lakshana	Grade
No itching	0
Mild (occasional itching but doesn't disturb routine activity)	1
Moderate (frequent itching, disturbs routine activity) Does not disturb sleep	2
Severe (Frequent itching that disturbs routine activity) Disturb sleep	3

2) **TODA:**

Lakshna	Grade
No Pricking pain	0
Mild (occasional itching but doesn't disturb routine activity)	1
Moderate (frequent itching, disturbs routine activity) Does not disturb sleep	2
Severe (Frequent itching that disturbs routine activity) Disturb sleep	3

3) **MANDALOTPATTI**

(UAS7- Urticaria Activity Score-7) as per Indian Journal of Dermatology³⁴

Lakshna	Grade
None	0
Mild < 20 wheals over 24 hrs	1
Moderate: 20-50 wheals over 24 hrs	2
Severe: > 50 wheals over 24 hrs or large area of wheals	3

Table No. 2: Criteria for overall Effect of Therapy

Complete Remission	100% relief in the sign and symptoms will be taken as complete remission
Marked Improvement	More than 76% improvement in the sign and symptoms will be taken as markedly improved.
Moderate Improvement	51 to 75% relief in the sign and symptoms will be taken as moderately improved.
Mild Improvement	26 to 50% relief in the sign and symptoms will be taken as mildly improved.
Unchanged	Result below 25% in the sign and symptoms will be considered as Unchanged



OBSERVATIONS AND RESULTS

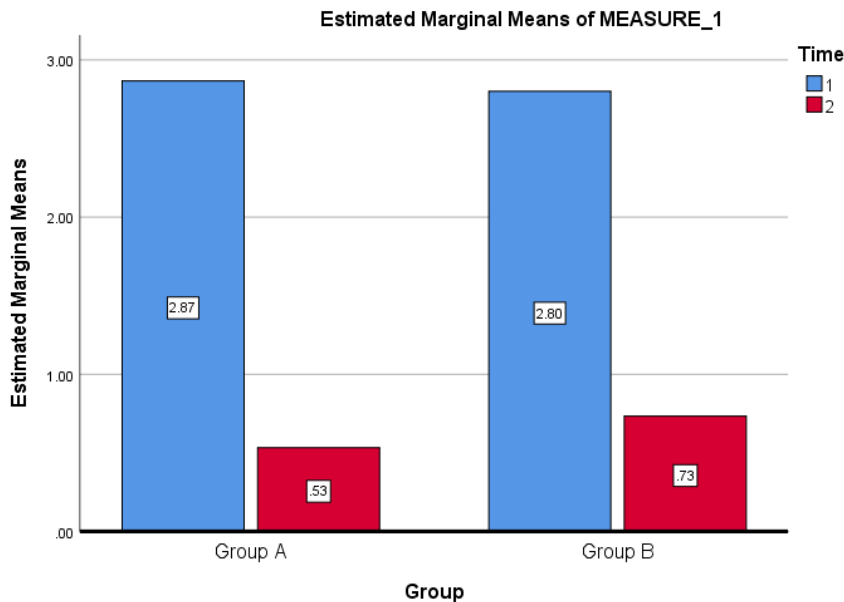
Demographics: In Group A, 60% of patients were in the 20–30 age group. 73% of Group A were female, indicating a higher prevalence in this gender within the study region.

KANDU

TABLE NO- 3

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	2.8667	.35187	15
	Group B	2.8000	.41404	15
	Total	2.8333	.37905	30
Post	Group A	.5333	.51640	15
	Group B	.7333	.59362	15
	Total	.6333	.55605	30

Group A and B had similar pre-test means (2.87 and 2.80, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 0.53 and Group B to 0.73. This indicates a greater improvement in Group A compared to Group B.



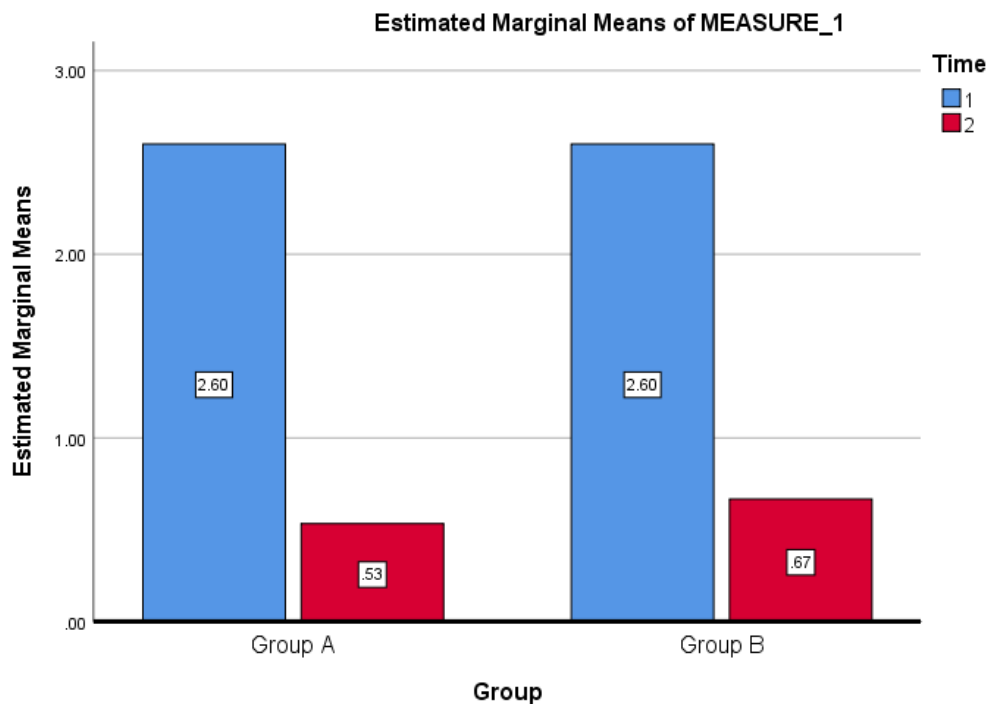
The graph shows a **decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test)** in both Group A and Group B. Group A's mean dropped from **2.87 to 0.53**, while Group B's mean decreased from **2.80 to 0.73**. This indicates improvement in both groups over time, with **Group A showing a slightly greater reduction** in scores than Group B.

TODA

TABLE NO- 5

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	2.6000	.50709	15
	Group B	2.6000	.50709	15
	Total	2.6000	.49827	30
Post	Group A	.5333	.51640	15
	Group B	.6667	.48795	15
	Total	.6000	.49827	30

Group A and B had similar pre-test means (2.60 and 2.60, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 0.53 and Group B to 0.67. This indicates a greater improvement in Group A compared to Group B



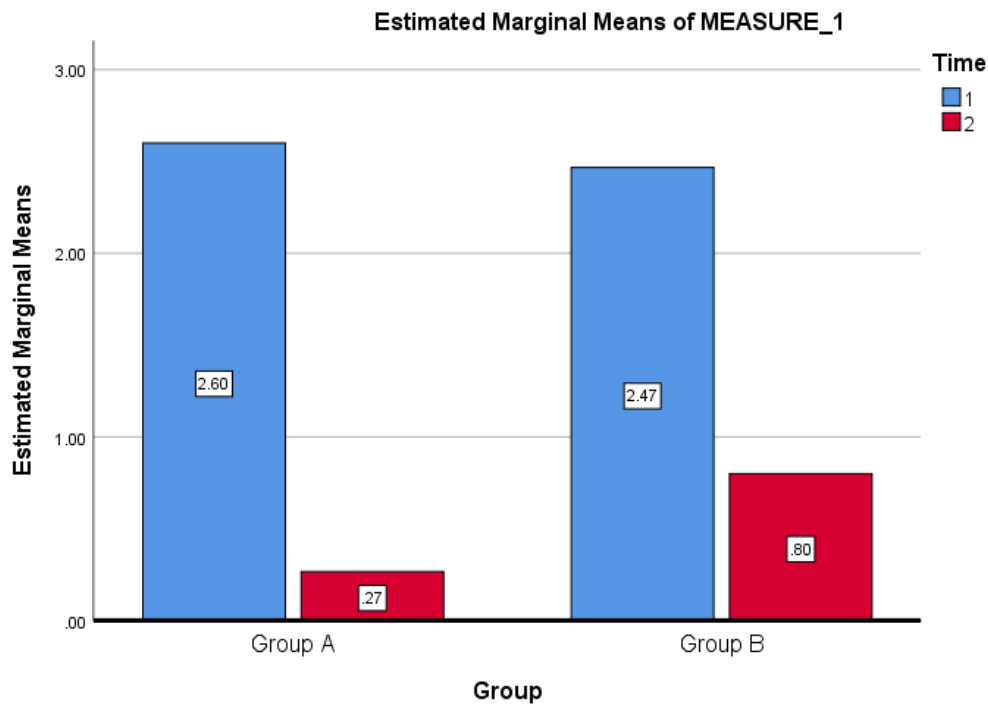
The graph shows a decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test) in both Group A and Group B. Group A's mean dropped from 2.60 to 0.53, while Group B's mean decreased from 2.60 to 0.67. This indicates improvement in both groups over time, with Group A showing a slightly greater reduction in scores than Group B.

MANDALOTPATTI

TABLE NO- 6

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	2.6000	.50709	15
	Group B	2.4667	.74322	15
	Total	2.5333	.62881	30
Post	Group A	.2667	.45774	15
	Group B	.8000	.56061	15
	Total	.5333	.57135	30

Group A and B had similar pre-test means (2.60 and 2.47, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 0.27 and Group B to 0.80. This indicates a greater improvement in Group A compared to Group B.



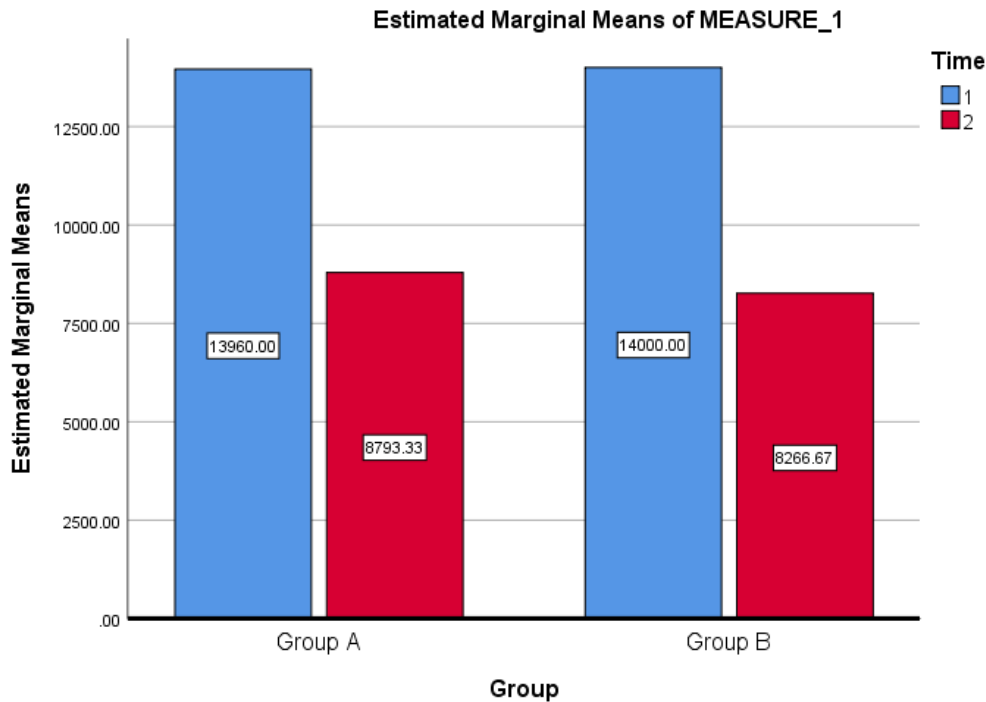
The graph shows a decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test) in both Group A and Group B. Group A's mean dropped from 2.60 to 0.27, while Group B's mean decreased from 2.47 to 0.80. This indicates improvement in both groups over time, with Group A showing a greater reduction in scores than Group B.

TLC

TABLE NO- 7

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	13960.0000	855.90387	15
	Group B	14000.0000	1133.89342	15
	Total	13980.0000	987.29865	30
Post	Group A	8793.3333	860.61993	15
	Group B	8266.6667	2153.62375	15
	Total	8530.0000	1633.51747	30

Group A and B had similar pre-test means (13960.00 and 14000.00, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 8793.33 and Group B to 8266.67. This indicates a greater improvement in Group B compared to Group A.



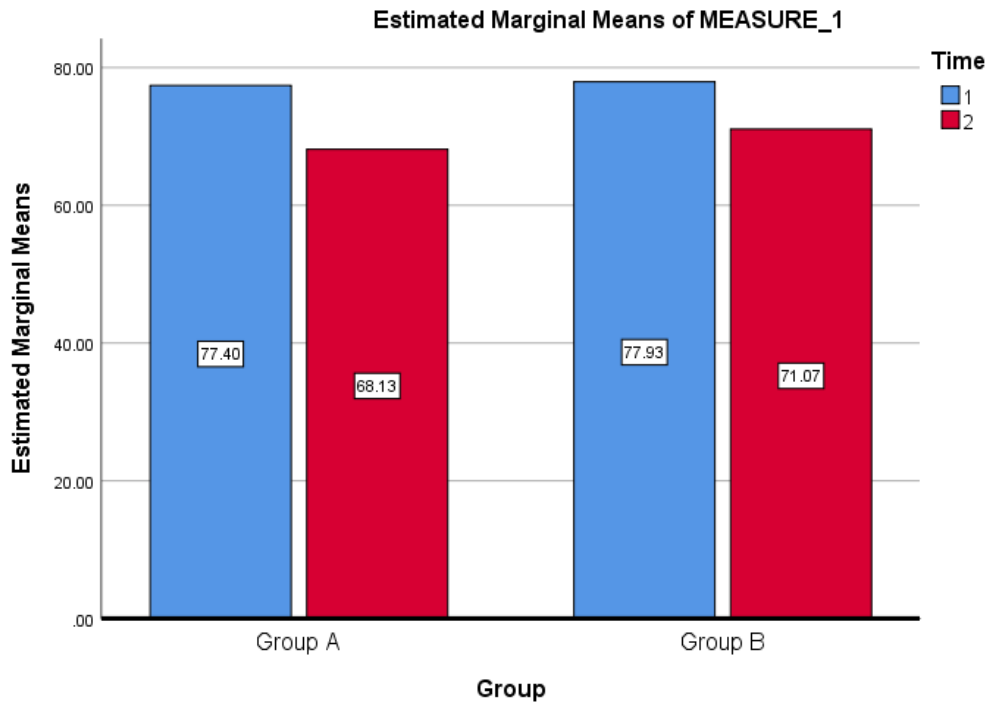
The graph shows a decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test) in both Group A and Group B. Group A's mean dropped from 13960.00 to 8793.33, while Group B's mean decreased from 14000.00 to 8266.67. This indicates improvement in both groups over time, with Group B showing a slightly greater reduction in scores than Group A.

NEUTROPHILLS

TABLE NO- 8

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	77.4000	2.02837	15
	Group B	77.9333	1.53375	15
	Total	77.6667	1.78757	30
Post	Group A	68.1333	4.82355	15
	Group B	71.0667	2.49189	15
	Total	69.6000	4.05650	30

Group A and B had similar pre-test means (77.40 and 77.93, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 68.13 and Group B to 71.07. This indicates a greater improvement in Group A compared to Group B



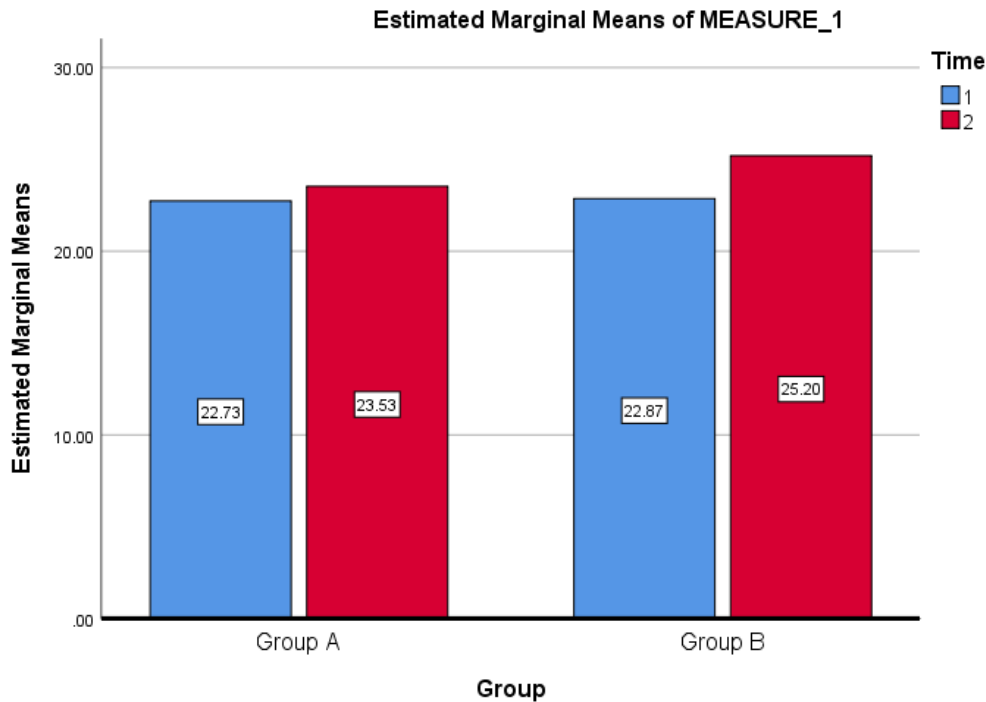
The graph shows a decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test) in both Group A and Group B. Group A's mean dropped from 77.40 to 68.13, while Group B's mean decreased from 77.93 to 71.07. This indicates improvement in both groups over time, with Group A showing a greater reduction in scores than Group B.

LYMPHOCYTES

TABLE NO-9

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	22.7333	11.70144	15
	Group B	22.8667	11.38211	15
	Total	22.8000	11.34232	30
Post	Group A	23.5333	3.60291	15
	Group B	25.2000	5.80886	15
	Total	24.3667	4.82439	30

Group A and B had similar pre-test means (22.73 and 22.87, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 23.53 and Group B to 25.20. This indicates a greater improvement in Group A compared to Group B.



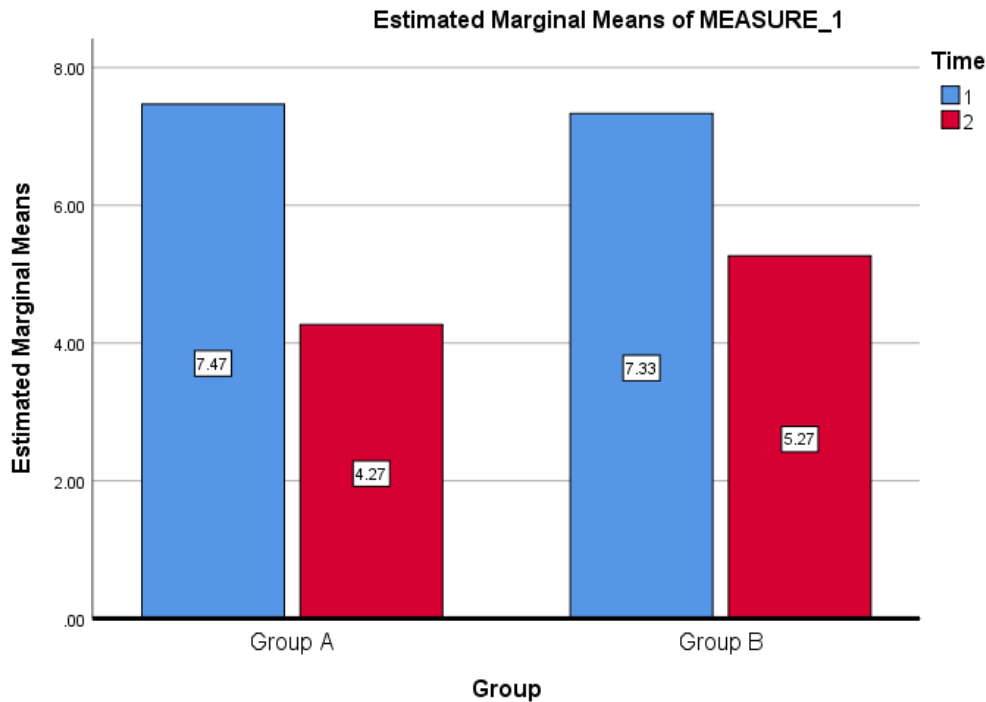
The graph shows a decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test) in both Group A and Group B. Group A's mean dropped from 22.73 to 23.53, while Group B's mean decreased from 22.87 to 25.20. This indicates improvement in both groups over time, with Group B showing a slightly greater reduction in scores than Group A.

EOSINOPHILLS

TABLE NO-10

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	7.4667	.63994	15
	Group B	7.3333	.48795	15
	Total	7.4000	.56324	30
Post	Group A	4.2667	.59362	15
	Group B	5.2667	.88372	15
	Total	4.7667	.89763	30

Group A and B had similar pre-test means (7.47 and 7.33, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 4.27 and Group B to 5.27. This indicates a greater improvement in Group A compared to Group B.



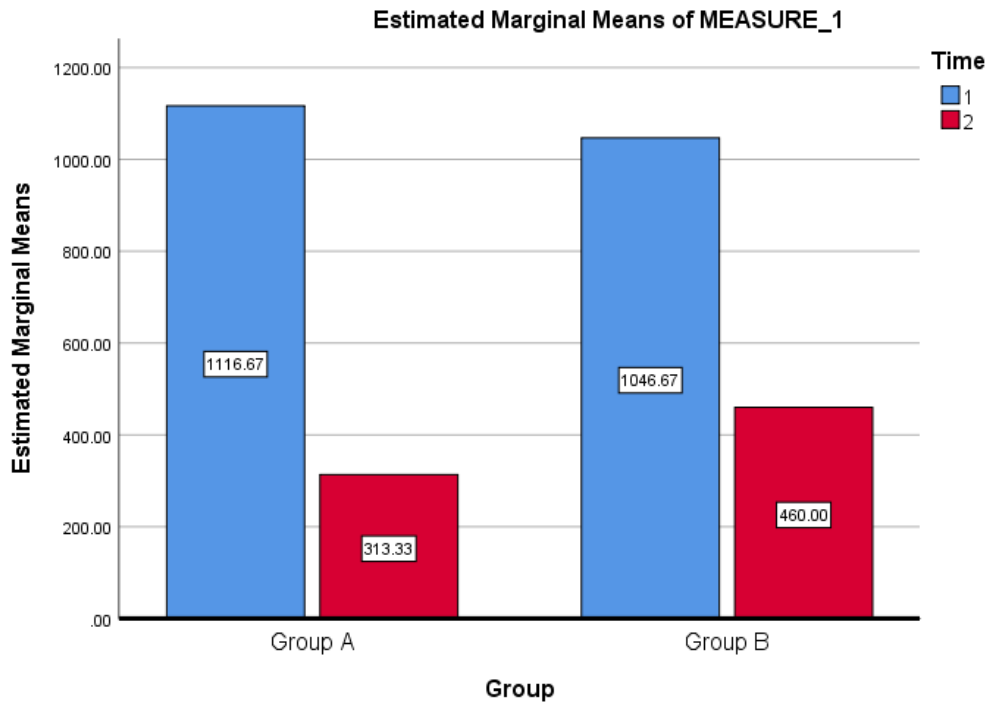
The graph shows a decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test) in both Group A and Group B. Group A's mean dropped from 7.47 to 4.27, while Group B's mean decreased from 7.33 to 5.27. This indicates improvement in both groups over time, with Group A showing a greater reduction in scores than Group B

AEC

TABLE NO- 11

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
Pre	Group A	1116.6667	130.47532	15
	Group B	1046.6667	164.17180	15
	Total	1081.6667	149.99042	30
Post	Group A	313.3333	130.20131	15
	Group B	460.0000	209.76177	15
	Total	386.6667	187.05215	30

Group A and B had similar pre-test means (1116.67 and 1046.67, respectively). After the intervention, both groups showed reduced scores, with Group A dropping to 313.33 and Group B to 460.00. This indicates a greater improvement in Group A compared to Group B.



The graph shows a decrease in mean scores from Time 1 (pre-test) to Time 2 (post-test) in both Group A and Group B. Group A's mean dropped from 1116.67 to 313.33, while Group B's mean decreased from 1046.67 to 460.00. This indicates improvement in both groups over time, with Group A showing a greater reduction in scores than Group B.

Comparative analysis of Group A and Group B

TABLE NO- 12

		Mean	N	Std. Deviation	Std. Error Mean	t-value	Sig.
KANDU	Group A	.53	15	.516	.133	-1.382	0.189
	Group B	.73	15	.594	.153		
TODA	Group A	.53	15	.516	.133	-1.000	0.334
	Group B	.67	15	.488	.126		
MANDALOTPAT TI	Group A	.27	15	.458	.118	-2.779	0.015
	Group B	.80	15	.561	.145		
TLC	Group A	8793.33	15	860.620	222.211	1.003	0.333
	Group B	8266.67	15	2153.624	556.063		
NEUTROPHILLS	Group A	68.13	15	4.824	1.245	-2.434	0.291
	Group B	71.07	15	2.4920	.643		
LYMPHOCYTES	Group A	23.53	15	3.603	.930	-1.335	0.203
	Group B	25.20	15	5.809	1.500		
EOSINOPHILLS	Group A	4.27	15	.594	.153	-3.240	0.006
	Group B	5.27	15	.884	.228		
AEC	Group A	313.33	15	130.201	33.618	-4.785	0.000
	Group B	460.00	15	209.762	54.160		

The present analysis compared the mean improvements across various clinical parameters between Group A and Group B, including *Kandu*, *Toda*, *Mandalotpatti*, *TLC*, *Neutrophills*, *Lymphocytes*, *Eosinophills* and *AEC*.

For *Kandu*, Group B showed a slightly higher mean (0.73) compared to Group A (0.53) but the difference was statistically insignificant (T= -1.382, P= 0.189)

In the case of *Toda*, Group B showed a slightly higher mean (0.67) compared to Group A (0.53), but the difference was statistically insignificant (T = -1.000, P = 0.334).

Similarly, *Mandalotpatti* showed a higher mean in Group B (0.80) than Group A (0.27), though this difference was significant (T = -2.779, P = 0.015).

Regarding biochemical markers, *TLC*, Group A recorded a mean of 8793.33, while Group B had 8266.67, with no significant difference (T = 1.003, P = 0.333).

Neutrophills values were slightly higher in Group B (71.07) than in Group A (68.13), but the T-value of 2.434 and P-value of 0.291 again indicated non-significance.

The *Lymphocytes* scores showed a minor difference (25.50 for Group B vs. 23.53 for Group A), which was statistically insignificant (T = -1.335, P = 0.203).

Eosinophills showed a higher mean in Group B (5.27) than Group A (4.27), but the T- value of -3.240 and P- value of 0.006 indicated statistically significant.

Lastly, *AEC* levels were slightly lower in Group A (313.33) compared to Group B (460.00), but this difference was highly significant (T = -4.785, P = 0.000).

Overall, the statistical analysis revealed that some of the measurements show significant differences between Group A and B parameters and some didn't show suggesting there are certain measurable factors where the groups are genuinely different.

DISCUSSION

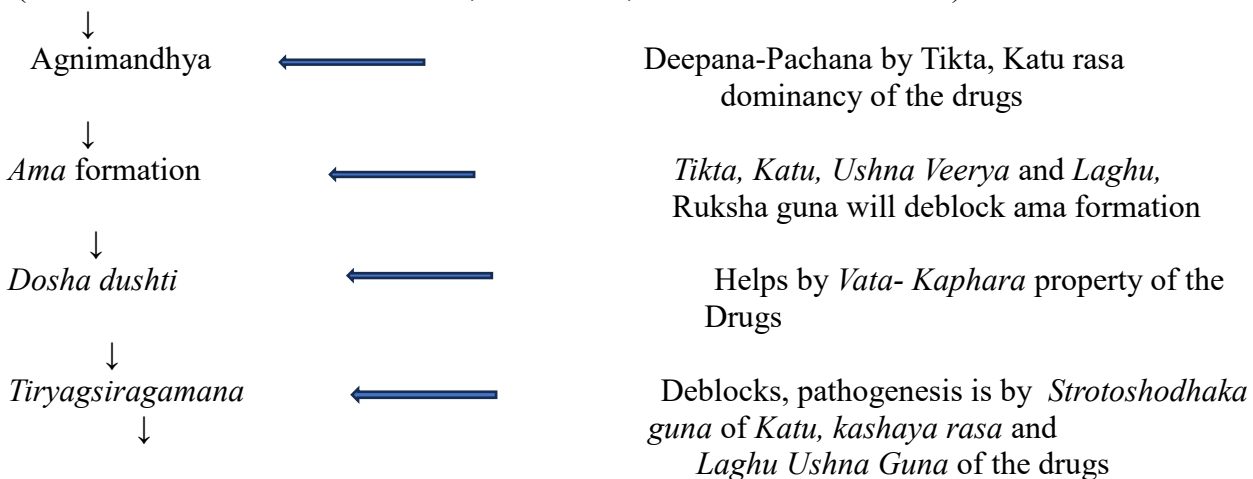
Sheetapitta involves *Agnimandya* (low digestive fire) and the formation of *Ama* (toxins). *Amritadi Yoga* works by breaking the *Samprapti* (pathogenesis) through its *Deepana-Pachana* and *Srotoshodhana* (channel-clearing) actions.

- **Amrita (Guduchi):** Acts as an immunomodulator and anti-allergic agent, stabilizing mast cells.
- **Haridra:** Provides antihistaminic effects and purifies the blood (*Raktaprasadana*).
- **Nimba:** Primarily addresses *Kandu* (itching) and skin inflammation.

SAMPRAPTI VIGHATANA (PROBABLE MODE OF ACTION)

Nidana Sevana

(Ahara-Vihara hetu like *Sheetambu*, *Anil Sevan*, *Katu-Amla-Lavana rasa*)



Srotodushti
(*Twak-Mamsa-Rakta* involvement)



Dilate strotas by *ushna veerya*
srotoshodhaka property of *katu rasa*

Vyadhi Utpatti (Shotha, Kandu, Daha)



Helps in the management of *Sheetapitta*

DISCUSSION ON RESULTS

The effect of the therapy in this study was assessed on the basis of changes observed in the cardinal features, laboratory findings after completion of the treatment.

1) EFFECT ON KANDU:

Impact of treatment on both groups w.r.t Kandu has demonstrated statistically significant results.

Group A

Mean values of Kandu assessed BT and AT were 2.87 and 0.53 respectively and the relief obtained on Kandu was 46% assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A.

Group B

In Group B, mean values of Kandu assessed BT and AT were 2.80 and 0.73 respectively and the relief obtained on Kandu was 33 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

Kandu mainly arises due to kapha – pitta dosha. The significant relief observed may be due to the *tikt kashaya rasa* and *kandughana* properties of the drugs.

2) EFFECT ON TODA:

Impact of treatment on both groups w.r.t Toda has demonstrated statistically significant results.

Group A

Mean values of Toda assessed BT and AT were 2.60 and 0.53 respectively and the relief obtained on Toda 46% was assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A.

Group B

In Group B, Mean values of Toda assessed BT and AT were 2.60 and 0.53 respectively and the relief obtained on Toda 33% was assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

Toda is the characteristic feature of vitiated Vata -Pitta Dosha. This significant relief may be due to the *Vata-pittahara* properties of the drugs.

3) EFFECT ON MANDALOTPATTI:

Impact of treatment on both groups w.r.t Mandalotpatti has demonstrated statistically significant results.

Group A

Mean values of Mandalotpatti assessed BT and AT were 2.60 and 0.27 respectively and the relief obtained on Mandalotpatti was 73% assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A.

Group B

In Group B, Mean values of Mandalotpatti assessed BT and AT were 2.47 and 0.80 respectively and the relief obtained on Mandalotpatti was 26% assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

The Mandalotpatti is caused due to presence of kapha – pitta dosha along with rakt dushti. The significant relief observed in Mandalotpatti due to the tridoshar property of the drugs.

4) EFFECT ON TLC

Impact of treatment on both groups w.r.t TLC has demonstrated statistically significant results.

Group A

Mean values of TLC assessed BT and AT were 13960.00 and 8793.33 respectively and the relief obtained on TLC was 80% assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A.

Group B

In Group B, Mean values of TLC assessed BT and AT were 14000.00 and 8266.67 respectively and the relief obtained on TLC was 80 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

This indicates that Amrita yoga (Kashaya) is effective in reducing the TLC Value .

5) EFFECT ON NEUTROPHILLS:

Impact of treatment on both groups w.r.t NEUTROPHILLS has demonstrated statistically significant results.

Group A

Mean values of NEUTROPHILLS assessed BT and AT were 77.40 and 68.13 respectively and the relief obtained on NEUTROPHILLS was 86 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A

Group B

In Group B, Mean values of NEUTROPHILLS assessed BT and AT were 77.93 and 71.07 respectively and the relief obtained on NEUTROPHILLS was 60% assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

This indicates that Amrita yoga (Kashaya) is effective in reducing the NEUTROPHILLS Value .

This indicates that Amrita yoga (Kashaya) is effective in reducing the NEUTROPHILLS Value .

6) EFFECT ON LYMPHOCYTES:

Impact of treatment on both groups w.r.t LYMPHOCYTES has demonstrated statistically significant results.

Group A

Mean values of LYMPHOCYTES assessed BT and AT were 22.73 and 23.53 respectively and the relief obtained on LYMPHOCYTES was 73 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A

Group B

In Group B, mean values of LYMPHOCYTES assessed BT and AT were 22.87 and 25.20 respectively and the relief obtained on LYMPHOCYTES was 46% assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

This indicates that Amrita yoga (Kashaya) is effective in reducing the LYMPHOCYTES Value.

7) EFFECT ON EOSINOPHILLS

Impact of treatment on both groups w.r.t EOSINOPHILLS has demonstrated statistically significant results.

Group A

Mean values of EOSINOPHILLS assessed BT and AT were 7.47 and 4.27 respectively and the relief obtained on EOSINOPHILLS was 73 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A

Group B

In Group B, mean values of EOSINOPHILLS assessed BT and AT were 7.33 and 5.27 respectively and the relief obtained on EOSINOPHILLS was 60 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

This indicates that Amrita yoga (Kashaya) is effective in reducing the EOSINOPHILLS Value .

8. EFFECT ON AEC

Impact of treatment on both groups w.r.t AEC has demonstrated statistically significant results.

Group A

Mean values of AEC assessed BT and AT were 1116.67 and 313.33 respectively and the relief obtained on AEC was 93 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$) in Group A

Group B

In Group B, mean values of AEC assessed BT and AT were 1046.67 and 460.00 respectively and the relief obtained on AEC was 60 % assessed after treatment which was statistically highly significant with p value ($p < 0.0001$).

This indicates that Amrita yoga (Kashaya) is effective in reducing the AEC Value

CONCLUSION

Amritadi Yoga is highly effective in reducing the symptoms of *Sheetapitta* and preventing recurrences. The trial drug showed superior results in managing acute itching compared to the standard *Haridra Khanda*. Ayurvedic management offers a safe, side-effect-free alternative to long-term antihistamine therapy.

REFERENCES:

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3. *Madhava Nidana* by Madhavakara with Madhukosha commentary.
4. *Bhaishajya Ratnavali*, Udarda-Sheetapitta-Kotha Chikitsa.