

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *DURVA-HARIDRA LEPA* AND *AMRITADI SYRUP* IN SHEETPITTA WITH SPECIAL REFERENCE TO URTICARIA IN CHILDREN**Dr. Abhishek Ghai^{1*}, Dr. Hem Parkash Sethi² and Dr. Ravi Dhaliya³**¹PG Scholar, Department of Kaumarbhirtiya, Babe Ke Ayurvedic Medical College and Hospital, V.P.O Daudhar, District Moga (Pb.) 142053.²Professor and H.O.D. Department of Kaumarbhirtiya, Babe ke Ayurvedic Medical College and Hospital, V.P.O Daudhar, District Moga (Pb.) 142053.³Assistant Professor, Department of Agada Tantra, Babe ke Ayurvedic Medical College and Hospital, V.P.O Daudhar, District Moga (Pb.) 142053.***Corresponding Author: Dr. Abhishek Ghai**

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ABSTRACT

Background: *Sheetapitta* (Urticaria) is one among the *Tvak Vikara* (Skin disease) that have similar *Hetu* (Cause) of *Kotha* and *Udarda*. *Vata* and *Kapha* are two "*Doshas*" (energies), which are primarily, disturbed which in turn is associated with *Pitta* resulting in *Tridosha Prakopa* (Aggravation of three energies) leading to redness, swelling itching on the skin etc. Symptoms include appearance of wheals all over the body with severe itching, burning sensation and pain. Symptomatology and causative factors of *Sheetapitta* can be considered similar to that of 'Urticaria'. **Aim:** This clinical study was carried out to evaluation of efficacy in *Sheetpitta* with special reference to chronic Urticaria. **Material and Methodology:** In this study include three Groups A, B, C. Each group take 15 child which select randomly. Data regarding Cardinal symptoms wise like- *Kandu* (Severe itching), *Vidaha* (Burning sensation), *Todabahula* (Severe pricking pain), *Raga* (Redness), *Chardi* (Vomiting), *Jwar* (Fever), Haematological, AEC, ESR and grading of assessment. *Durva-haridra* for local application thrice a day and *Amritadi* syrup in dose according age for 5years child 5ml, for 5-10 years child 7.5ml for 12 year child 10ml twice a day with *Madhu anupan* after meal was evaluated. **Observation and Results:** Out of 45 patients 15% patients showed mild improvement, 45% patients were moderately improved, were as 40% patients were markedly improved. The result of follow up study of all groups showed that the chances of recurrence of disease were very less in C group. ESR mean score before treatment was 15.7 which was reduced to 10.5 after treatment with difference of 5.15 having p value<0.001. AEC mean score before treatment was 445 which was reduced to 243 after treatment with difference of 202, value of p<0.001. **Conclusion:** External use of *Durva-Haridra Lepa* and internal *Amritadi Syrup*, showed maximum cure in the patients of Chronic Urticaria, as well as it prevented recurrence. Thus there is scope for *Ayurvedic* management in chronic stage than in acute stage, as Acute Urticaria has specific cause and there are high chances of spontaneous reoccurrence, whereas chronic Urticaria can be managed accordingly by various detoxification, immune-modulatory, anti-inflammatory and antioxidant *Ayurvedic* herbal formulations.

KEYWORDS: *Sheetpitta, Koth, Udard, Tridosha Prakop, Urticaria, Durva-Haridra Lepa and Amritadi Syrup.***INTRODUCTION**

Urticaria is such a widespread debilitating condition having highest impact on quality of life and required most visits to the Emergency Department. It affects about 15-20 % of total population.^[1] It is a vascular reaction characterized by transient, erythematous swelling over the skin and/or on mucus membranes which may appear on any part of the body. They are usually transient and resolve in a few hours.^[2] It makes

the patient restless due to severe itching burning sensation and pain.

In present life style, one can't follow the rules of '*Dinacharya*' (Daily regimen) and '*Ritucharya*' (Seasonal regimen) described in '*Ayurveda*'. Due to industrialization and traffic one constantly comes into contact with various pollutants. The spicy and fast food eaten now a days, which have very less nutritional values and also having similar properties to '*Viruddhahara*' (Incremental). These all ultimately resulted into

'*Dhatudurbalya*' (Tissue debilitation), which causes sensitization towards allergens as well as antibodies and produces various types of allergic reactions, one of them is '*Urticaria*', which is very common. The symptoms of Urticaria are similar to *Sheetpitta-Udarda-Kotha*.

Skin allergies frequently cause rashes, or swelling and inflammation within the skin, which is known as a "wheal and flare" reaction characteristic of hives (Urticaria) and angioedema. Itching is a common characteristic of nonexfoliative skin disorders; these may be associated with burning sensation, change of colour etc. Out of these nonexfoliative skin diseases *Sheetpitta* (Urticaria) is one of the common dermatoses found all over the world. In Ayurveda, allergic manifestation is mentioned under the concept of *Satmya-asatmya* (Beneficial-non beneficial).^[3] It manifests due to exposure to *Asatmya Ahara-vihara* (Non beneficial diet and regimen) and contact with different poisonous materials (allergens). Symptoms of allergic skin reaction is mentioned as *Kotha* in Brihata Trayi later on it is developed as separate disease under the title *Sheetapitta-Udarda Kotha* by Acharya Madhavakara.^[4] As the name *Sheetpitta* suggests the involvement of *Vata* and *Pitta Doshas*, along with *Rasa* and *Rakta dhatus*. As it is a very distressing, frustrating and challenging dermatological condition with no satisfactory treatment.^[6] This study is taken to explore effective remedy for above condition. Here the study is selected to find out simple, sure and effective medicament for *Sheetpitta* which have least or no side effect. For this purpose, *Durva-Haridra Lepa and Amritadi Syrup* from Bhaishjya ratnawali is selected for study in chronic urticarial.^[5]

AIM AND OBJECTIVES

1. To study the effect of Durva-Haridra Lepa and Amritadi syrup in the management of sheetpitta.
2. To compare the effect of single or in combination treatment.

MATERIAL AND METHODS

Source of Material

Minimum of 45 patients between 5-12 Years of age fulfilling the inclusion criteria were selected for this clinical study of *Sheetpitta* (urticaria) from Kaumarbhritya OPD and IPD and adjoining school.

Inclusive criteria

1. Children aged between 5-12years

Table no. 1: No Of Participants & Trail Drug.

GROUPING	GROUP A	GROUP B	GROUP C
Subject	15	15	15
Drug	Durva-haridra lepa	Amritadi Syrup	Amritadi Syrup and Durva-haridra lepa
Duration	1 month	1 month	1 month
Follow up	2 : after 15 days	2 : after 15 days	2 : after 15 days

2. Patients showing and also with history of classical clinical features like - Kandu, Toda, Mandalapti, Daha, Jawar, Chardi.
3. Sheetpitta (Urticarial rashes).
4. Patient or parents willing for trial.

Exclusive 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.
6. Patients above or below the mentioned age group.

Criteria for withdrawal

1. Non compliance of the drug.
2. Patient or parents wants to withdrawn from trial himself or herself.
3. Adverse drug reaction leading to admission in hospital may be withdrawn.

Investigations

Before commencement of medication and after completing the medication HB%, ESR, Absolute Eosinophil count (AEC) was investigated.

Drug Details

- 1) *Durva haridra lepa* – *Durva & Haridra*
- 2) *Amritadi syrup* – Contains *Durva (Cynodon Dactylon)*, *Haridra (Curcuma Longa)*, *Giloy (Tinospora Cordifolia)*, *Dhurlabha (Fagonia Cretica)*, *Nimba (Azadiractan Indica)*, And Honey.

STUDY DESIGN

Randomized control trial Randomized control trial:

After Institutional Ethical Committee Approval, Forty five patients of *Sheetpitta* is selected for further study in three randomly selected groups i.e. group A, group B and group C from OPD and IPD of Babe Ke Ayurvedic Medical College And Hospital, Daudhar, Moga, Punjab. *Durva-haridra lepa* and *Amritadi syrup* was prepared in *Rasashala* of *Rasa Shastra* Department of Babe Ke Ayurvedic Medical College and Hospital, Daudhar, Moga, Punjab.

INTERVENTION**Table no. 2: The Dose and time of administration of Formulation.**

S no.	Formulation	Dose	time of administration
1.	Durva-haridra lepa	Lepa was prepared with water & locally applied	thrice a day For half an hour
2.	Amritadi syrup	5years child 5ml,	Twice a day After meal
		5-10 years child 7.5ml	
		12 year child 10ml	

Assessment Criteria

The patients were treated for continuous 1 month with 1 follow up after 15 days and the assessment was done according to grading of cardinal symptoms like- Kandu (Severe itching), Vidaha (Burning sensation), Todabahula (Severe pricking pain), Raga (Redness), Chardi (Vomiting), Jwar (Fever).

Grading for assessment.

1. Kandu	
No	0
Mild	1
Moderate	2
Severe	3
Unbearable and disturbing routine	4
2. Toda	
No	0
Mild	1
Moderate	2
Severe	3
Unbearable and disturbing routine	4
3. Daha	
No	0
Mild	1
Moderate	2
Severe	3
Unbearable and disturbing routine	4
4. Mandalopatti	
No	0
25% of skin involvement	1
26-50% skin involvement	2
51-75% skin involvement	3
>75% skin involvement	4
5. Frequency of attack	
No	0
Once in 4-5 days	1
Once in alternate day	2
Once in daily	3
Twice daily	4
6. Associated symptoms like Jwara, Pipasa, Aruchi, Chhardi etc.	
No	0
Mild	1
Moderate	2
Severe	3
Unbearable	4

OBSERVATION AND RESULTS

The data obtained was coded and entered into Microsoft Excel Worksheet. The data was analyzed by using frequency distribution, descriptive statistics, analysis of variance with the help of statistical software SPSS and tabulated as below.

RESULTS AND OBSERVATION**Table no 3: Distribution of participants based on Kandhu (before treatment).**

Kandhu (Itching)	No. of Patients			Total	%
	A	B	C		
No	0	0	0	0	0
Mild	4	5	4	13	84.33
Moderate	8	7	9	24	94.33
Severe	3	3	2	8	26.67
Unbearable and disturbing routine	0	0	0	0	0

Table no. 4: Distribution of participants based on Todabahula (before treatment).

Todabahula (Severe pricking pain)	No. of Patients			Total	%
	A	B	C		
No	0	0	0	0	0
Mild	4	4	2	10	33
Moderate	8	7	9	24	94.33
Severe	3	4	4	11	37
Exhaustion even on rest	0	0	0	0	0

Table no. 5: Distribution of participants based on Vidaha (before treatment).

Vidaha (Burning Sensation)	No. of Patients			Total	%
	A	B	C		
No	0	0	0	0	0
Mild	6	4	3	13	84.33
Mode	6	8	9	23	93.33
Severe	3	3	3	9	30
Exhaustion even on rest	0	0	0	0	0

Table no. 6: Distribution of participants based on Raga (before treatment).

S no.	Formulation	Dose	time of administration
1.	Durva-haridra lepa	Lepa was prepared with water & locally applied	thrice a day For half an hour
2.	Amritadi syrup	5years child 5ml,	Twice a day After meal
		5-10 years child 7.5ml	
		12 year child 10ml	

Table no. 7: Distribution of participants based on Chardi (before treatment).

Chardi (Vomiting)	No. of Patients			Total	%
	A	B	C		
No	0	0	0	0	0
Mild	4	5	4	13	84.33
Moderate	8	7	9	24	94.33
Severe	3	3	2	8	26.67
Exhaustion even on rest	0	0	0	0	0

Table no. 8: Distribution of participants based on Jwar (before treatment).

Jwar (Fever)	No. of Patients			Total	%
	A	B	C		
No	0	0	0	0	0
Mild	4	5	2	11	37
Mode	7	8	8	23	93.33
Severe	4	2	5	11	37
Exhaustion even on rest	0	0	0	0	0

Table no. 9: Effect of trial drug Dhurva-Haridra Lepa within the Group A.

GROUP A	Dhurva-Haridra Lepa	
	BT	AT
Mean	28.55	27.88
S.D.	1.199	1.168
Number	10	10
Mean Difference	0.67	
T Paired Test	4.586	
P value	0.001	
Table Value at 0.05	2.26	
Result	Significant	

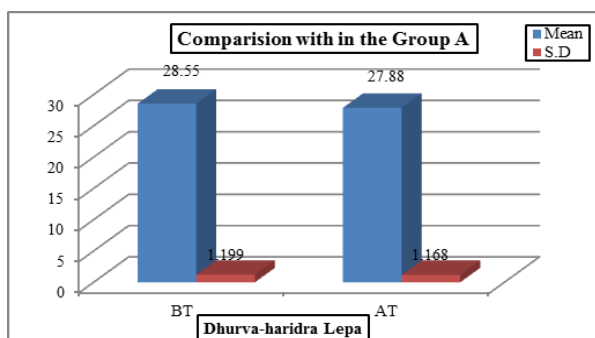


Figure 1: Effect of Trial Drug Dhurva-Haridra Lepa within the Group A.

Table no. 10: Effect of trial drug Amritadi Syrup within the Group B.

GROUP B	AMRITADI SYRUP	
	BT	AT
Mean	29.31	28.68
S.D.	1.762	1.460
Number	10	10
Mean Difference	0.63	
T Paired Test	3.417	
P value	0.008	
Table Value at 0.05	2.26	
Result	Significant	

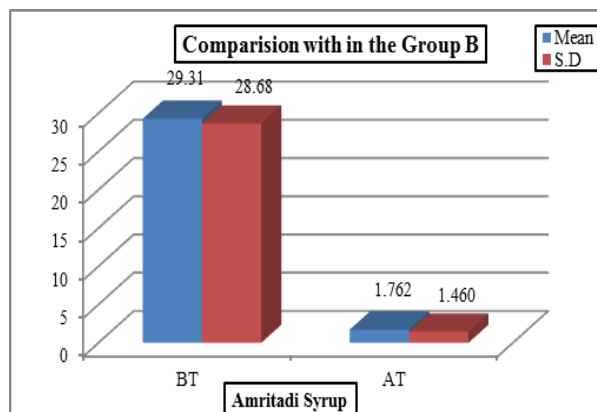


Figure 2: Effect of Trial Drug Amritadi Syrup within the Group B.

Table no. 11: Effect of trial drug Dhurva-Haridra Lepa & Amritadi Syrup within the Group C.

Group C	Dhurva-Haridra Lepa & Amritadi Syrup	
	BT	AT
Mean	29.04	27.21
S.D.	0.903	1.005
Number	10	10
Mean Difference	1.83	
T Paired Test	15.106	
P value	0.000	
Table Value at 0.05	2.26	
Result	Significant	

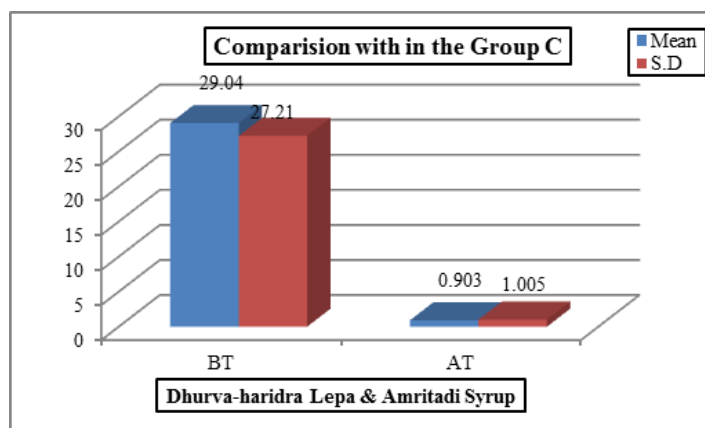


Figure 3: Effect of Trial Drug Dhurva-Haridra Lepa & Amritadi syrup with in the Group C.

Table no. 12: Effect of overall therapy on Haematological Investigations between the groups.

Haematological Values	Mean Score		Difference of Mean	SD ±	SE±	t value	p value
	BT	AT					
Hbgm%	12.37	12.62	0.25	1.446	0.323	0.773	>0.05
TLC	8385	7900	485	2190.24	489.75	0.990	>0.05
ESR	15.7	10.55	5.15	3.646	0.815	14.851	<0.001
AEC	445	243	202	97.473	21.796	9.263	<0.001

Table no. 13: Analysis of trial according Symptoms after 15 day Followup.

S.No	Symptoms on followup	Group A		Group B		Group C		Total	%
		N	%	N	%	N	%		
1.	Vidaha (Burning Sensation)	0	0	2	20	2	20	4	13.33
2.	Todabahula (severe pricking pain)	3	30	1	10	2	20	6	20
3.	Jwara (Fever)	4	40	2	20	1	10	7	23.33
4.	Mandalopatti (Wheal over skill)	3	30	3	30	3	30	9	30
5.	Chardi (Vomiting)	0	0	1	10	0	0	1	3.33
6.	Kandu bahulya (severe itching)	4	40	6	60	7	70	17	57

Table no. 14: Overall effect of therapy based on improvement.

Result	No of patients	Percentage
Cured (100%)	0	0
Marked Improvement (75-100%)	30	104.33
Moderate improvement(50-75%)	10	33
Mild improvement(25-50%)	5	16.67
No relief(<25%)	0	00

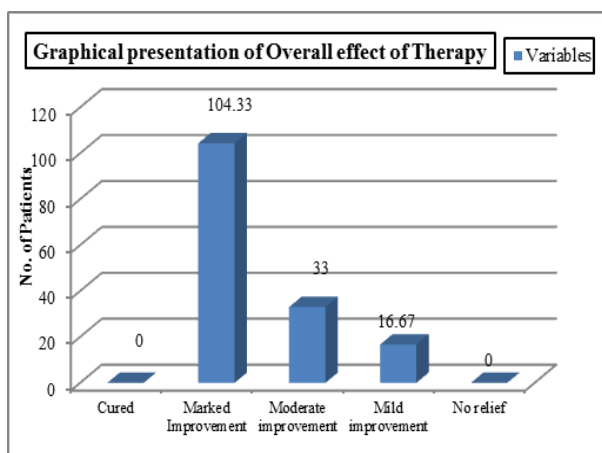


Figure 4: Overall effect of therapy.

DISCUSSION

Effect of therapy on Kandu

Mean B.T score was 3.25 which got reduced to 0.65 after trial, with the mean difference of 2.6 showing the result of 80%,SD ±0.945, SE +- 0.211 with ‘t’ value 12.75 at p value, 0.001 which is highly significant. Relief in Kandu may be due to Kaphahara actions of trial drug and also due to antimicrobial & antiallergic properties of Haridra.

Effect of therapy on Toda

B.T Of Mean score of toda was 3.3 which got reduced to 0.85 after trial, with the mean difference of 2.45 showing the result of 74.24%, SD±0.769, SE±0.176 with ‘t’ value 13.732 (p<0.001) which is highly significant. Relief in

Toda may be due to Vedana sthapana and Vatanulomana actions of Agnimantha.

Effect of therapy on Daha

In Daha the Mean B.T score was 3.45 which got reduced to 0.65 after trial, with the mean difference of 2.8 showing the result of 81.15%, SD ± 0.834 , SE ± 0.192 with 't' value 14.851 ($p < 0.001$) which is highly significant. Relief in Daha may be due to Dahaprashmana action of Durva.

Effect of therapy on Mandalautpati

Mean B.T score of mandalautpati was 2.9 which got reduced to 0.75 after trial, with the mean difference of 2.15 showing the result of 74.13%, SD ± 0.988 , SE ± 0.221 with 't' value 19.73 ($p < 0.001$) which is highly significant. This relief may be due to Shothahara actions of Haridra and Agnimantha.

Effect of therapy on Frequency of Attack

On frequency of attack the Mean B.T score of was 2.25 which got reduced to 0.75 after trial, with the mean difference of 1.5 showing the result of 66.66%, SD ± 0.607 , SE ± 0.136 with 't' value 11.05 ($p < 0.001$) which is highly significant.

Effect of therapy on associated Symptoms

Mean B.T score was 2.85 which got reduced to 0.8 after trial, with the mean difference of 2.05 showing the result of 71.92%, SD ± 0.826 , SE ± 0.185 with 't' value 11.105 ($p < 0.001$) which is highly significant.

II. Effect of Therapy on Objective Parameter

During the study, maximum biochemical parameters before and after treatment were unchanged, but variation in the values of ESR and AEC were found, which is given as below:

- ❖ In case of ESR mean score before treatment was 15.7 which was reduced to 10.5 after treatment with difference of 5.15 having p value < 0.001 shows statistically highly significant results.
- ❖ In case of AEC mean score before treatment was 445 which was reduced to 243 after treatment with difference of 202, value of $p < 0.001$. Hence it shows statistically highly significant results.

OVERALL EFFECT OF THERAPY

- ❖ Total 45 patients were registered and divided into three groups A, B, C which mentioned. All the patients completed the full course of trial. Out of 45 patients 15% patients showed mild improvement, 45% patients were moderately improved, were as 40% patients were markedly improved. The result of follow up study of all groups showed that the chances of recurrence of disease were very less in C group.
- ❖ Comparison of the results of the three groups showed that amritadi syp and durvaharidradi lepa provided better relief in all the signs, symptoms and overall improvement, in comparison to Shamana group.

- ❖ The results of follow up study of all the groups showed that the chances of recurrence of the disease were very less in C group. One of the main aims of this study was to ascertain that whether
- ❖ In *Sheetapitta*, due to exposure to cold wind, *kapha* & *vata* become vitiated and when they combine with *pitta* it spreads. Thus it is a *Pitta Pradhana Tridoshajavyadhi* caused by the contact of *Sheetalamaruta*.
- ❖ *Rasayana* plays any role in the management of the disease. For that it was also planned to administer *Amritadi* syrup. The elaborate analysis of the result of this study also showed that when *Rasayana* like, *amritadi* syp was administered, the cure rate was remarkably high. The recurrence rate in *Rasayana* group was also less.
- ❖ *Durva* and *haridra* have *Katu*, *Tikta*, *Kashaya rasa* & *Laghu*, *Ruksha guna* which are *Kapha shamak*. According to *Doshprashmana* properties *Durva* is *Kapha-pitta shamak* and *haridra* is *kapha-vatashamak*.
- ❖ *Giloy*, *Dhuslabha* and *Nimb* have *Tikta*, *Kashaya rasa* and *Ushana virya*. It has *Deepan* and *Pachan* properties. Due to *Deepana*, *Pachan* properties it corrects the vitiated *pachaka pitt* and helps in purifying *Raktadhatu* and thereby combating *Raktadushti*. *Pachaka Pitta* controls other *Pitta* in the body including *Bhrajak Pitta* which is also vitiated in *sheetapitta*. The antioxidant properties of all *dravyas* the nature of relief and stops the recurrences. All *Dravyas* have *dosha-prabhava* properties like *Kaphapittahara*, *Tridoshashamaka*, *Vatapittashamaka*, *Kaphapittashamaka* which play important role for subside *sheetpita* and stops the recurrences.
- ❖ *Most of drugs are Tikta Rasa Pradhana*, by its *Vishahara* property it helped in detoxification of accumulated toxins in the form of histamines and leukotriens, by its *Krimighna* property acted as anti-parasitic agent, by its *Dahahara* and *Kanduhara* action it pacified the symptoms of itching and burning sensation produced by the nerve stimulation, *Kushta Prashamaka* and *Twak Mamsa Sthirakaraka* action helped in normalising the skin by reducing the urticarial lesions.

CONCLUSION

On the basis of above results, it can be concluded that, when *Amritadi* syrup and *dhurva-haridra lepa* (group c) is administered, maximum cure can be obtained in the patients of *Chronic Urticaria*, as well as its recurrence can be prevented. Thus there is scope for *ayurvedic* management in chronic stage than in acute stage, as acute *urticaria* has specific cause and there are high chances of spontaneous reoccurrence, whereas *chronic Urticaria* can be managed accordingly by various detoxification, immune-modulatory, anti-inflammatory and antioxidant *Ayurvedic* herbal formulation.

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