

EFFECT OF HERBAL COMPOUNDS IN THE MANAGEMENT OF *VICARCIKĀ* (ATOPIC DERMATITIS): A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Skin is the largest protective organ of the body. A healthy skin is the mirror image of a good health. It acts as an effective barrier against the entry of diseases. Skin diseases like atopic dermatitis/eczema get a suitable atmosphere especially in developing countries, due of fast life style, industrial and occupational hazard, Unhygienic living condition, Polluted environment, repeated use of chemical additives etc. This type of diseases make a person feels much more humiliation in society because with a presence, no one wants to touch them, forbidden by everyone and beauty and personality loss, which leads to under stress. Due to above mentioned cause this disease was chosen for the study. The study was conducted in 45 clinically diagnosed patients of

vicarcikā (atopic dermatitis) and randomly divided in to into three groups. Namely group A, B and C. Each group has 15 patients. Group A: *arka taila* (external application) as required twice daily for 45 days. Group B: *viḍamgādi cūrṇa* (5gm.) orally, twice daily for 45 days. Group C: Both *arka taila* (external application) and *viḍamgādi cūrṇa* (orally) will be given. After 45 days of study, Group C showed very good effect on disease comparisons to Group A and Group B, because in it internal as well as external medications were use; so it showed better result.

KEYWORD: *vicarcikā*, Atopic dermatitis, Herbal compounds, *arka taila* and *viḍamgādi cūrṇa*.

INTRODUCTION

vicarcikā is *kapha* predominant disease.^[1] In *āyurveda* it includes in vast umbrella of *kuṣṭha roga* under title of '*kṣudra kuṣṭha*.^[2] Atopic dermatitis is an acute or chronic inflammatory condition of the superficial skin marked early by redness and itching with the formation of minute papules and vesicles which soon rupture through which the serum exudates on the surface of the skin which afterwards dries up and forms crust. It is called as the Dry eczema. When the swelling of the epidermis resolves before the vesication and oozing occurs, it is known as the weeping eczema.^[3]

We face a very exciting and very optimistic time in the treatment of eczema or atopic dermatitis. Initially we thought eczema- an inflammatory skin disease that affects 4-7% of adult and 15-25% of children worldwide with the highest number in Asia were caused by defects in the epidermal skin barrier or the outer layer of skin.

Atopic dermatitis is an immune driven disease that in turn causes secondary defects in the epidermal barrier. In the 8 out of 10 cases eczema has a genetic background and family history of eczema and seasonal allergies. The prevalence of skin diseases (Atopic dermatitis) in the general population has varied from 7.86- 11.16% in various studies.^[4] It also pose huge financial, psychological burden for the patients and their family. However, there are very minimal data available on the prevalence of the skin disease in this population, especially in the rural India. Improvement in standard of living, education of the general public, improvement in the environmental sanitation, and good nutritious food may help us to bring down the skin disease in this area.

Generally atopic dermatitis is treated by topical antibiotics, antifungal and steroid drugs but there are still very large unmet needs for the treatment of eczema. So, *āyurveda* medicine might be effective to deal with this problem. Thus this clinical trial has been selected to make the better options to treat the Atopic dermatitis by "*arka taila* and *viḍaṃgādi cūrṇa*."

AIMS AND OBJECTIVE

1. To evaluate the clinical efficacy of "*arka taila* and *viḍaṃgādi cūrṇa*" in *vicarcikā*.

STATEMENT OF HYPOTHESIS**Null Hypothesis**

Interventions of *arka taila* and *viḍamgādi cūrṇa* do not have any remarkable effect on *vicarcikā*.

Alternate Hypothesis

There is difference present before and after intervention of *arka taila* and *viḍamgādi cūrṇa* on *vicarcikā*.

MATERIAL AND METHOD

a) Source of data - Subjects was randomly selected irrespective of age, sex, religion, education, socio economic status & occupation from OPD of NIA Aarogyashala & SSBH.

b) Study design – open labeled randomized clinical trial

c) Sample size - 45 clinical diagnosed subjects were randomly selected and into three groups. Namely group A, B and C. Each group has 15 patients.

Group A: *arka taila* (external application) as required twice daily for 45 days.

Group B: *viḍamgādi cūrṇa* (5gm.) orally, twice daily for 45 days.

Group C: Both *arka taila* (external application) and *viḍamgādi cūrṇa* (orally) will be given.

d) Drugs - Both *arka taila*^[5] (external application) and *viḍamgādi cūrṇa*^[6] (orally) were prepared in the Pharmacy of National Institute of Ayurveda, Jaipur.

e) Dose - *arka taila* (external application) as required and *viḍamgādi cūrṇa* (5gm.) orally, twice daily for 45 days.

f) Time period of Clinical trial – Total duration of clinical trial was 45 days.

g) Follow up – Follow-up of patient was done on 15th, 30th and 45th days of treatment. Improvement in the symptoms if any and other effects were noted down.

Laboratory investigations were repeated in Group, Group B and Group C after completion of the treatment.

The collected data will be analyzed statistically.

Ethical Clearance – This study was approved by Institutional Ethical committee (IEC) of National Institute of Ayurveda, Jaipur letter no. IEC/ACA/2017/97; dated 26/04/2017 and also registered in Clinical trial registry - India CTRI no - CTRI/2018/06/014446 before starting the clinical trial on patients of *Vicarcikā* (Atopic dermatitis).

Inclusion Criteria

1. Patient of either sex between 16 to 70 years of age.
2. Patient having clinical sign & symptoms of *Vicarcikā* according to *āyurveda* and Eczema according to modern system of medicine.
3. Patients who are ready to sign consent form.
4. Patients having complaints less than 5 year of duration.

Exclusion Criteria

1. Patient below 16 years & above 70 years of age.
2. Patient with long term steroid and cytotoxic treatment.
3. Patient is suffering from serious illness of any system.

Withdrawal Criteria

1. Any major diseases necessary to start new treatment modality.
2. If patient wants to withdraw from the trial.
3. Adverse drug reaction if seen in any patient then it will be withdrawn from the trial.

Criteria for assessment

1. Classical signs & symptoms of *Vicarcikā* (Atopic Dermatitis) according to *āyurveda*^[7] and Modern system of medicine.
2. A special Performa was prepared incorporating all the signs & symptoms of *Vicarcikā* and Atopic dermatitis as well as the *duṣṭi lakṣaṇa of doṣa, duṣya, srotas, agni* etc. On the basis of the Performa, all the patients of the present study were examined in detail.

1) Subjective Criteria – **Scoring criteria for assessing vicarcikā****1. kaṇḍū (pruritis)**

- 0 - No itching
- 1 - Mild itching not disturbing normal activity
- 2 - Occasional itching disturbs normal activity
- 3 - Itching present continuously & even disturbing sleep

2. dāha (burning)

- 0 - No burning sensation
- 1 - Mild type of burning not disturbing normal activity
- 2 - Occasionally burning disturbing normal activity

3 - Burning present continuously & even disturbing sleep

3. *srāva* (Oozing)

0 - No discharge

1 - Occasional discharge after itching.

2 - Occasional oozing without itching.

3 - Excessive oozing making clothes wet

4. *rūkṣatā* (Dryness)

0- No dryness

1- Dryness with rough skin (*Ruksha*)

2- Dryness with scaling (*Khara*)

3- Dryness with cracking (*Parusha*)

5. *Pidikotpatti* (Eruption)

0 - No eruption in the lesion

1 - Scanty eruptions in few lesions

2 - Scanty eruptions in at least half of the lesion

3 - All the lesions full of eruption

6. *vaivarṇyatā* (Discolouration)

0 - Nearly normal skin colour

1 - Brownish red discoloration

2 - Blackish red discoloration

3 - Blackish discoloration

7. *rāji* (Thickening of skin)

0 - No thickening of skin

1 - Thickening of skin but no criss-cross marking

2 - Thickening with criss-cross marking

3 - Severe lichenification

EASI (Eczema Area and Severity Index) score: The intensity of redness (erythema), thickness (infiltration, papulation, and oedema), scratching (excoriation) and lichenification (lined skin) of the eczema is assessed as none (0), mild (1), moderate (2) and severe (3). Half scores are allowed.

Area of involvement

0	1	2	3	4	5	6
No eruption	< 10%	10-29%	30-49%	50-69%	70-89%	90-100%

Table No 1: Subjective Criteria of vicarcikā (Atopic dermatitis).

Erythema	(E)
0	None
1-Mild	Faintly detectable erythema: very light pink
2- Moderate	Dull red clearly distinguishable
3-Severe	Deep/ dark red
Infiltration/ population	(I)
0	None
1-Mild	Barely perceptible elevation
2- Moderate	Clearly perceptible elevation but not extensive
3-Severe	Marked and extensive elevation
Excoriation	(Ex)
0	None
1-Mild	Scant evidence of excoriation with no sign of deeper skin damage (erosion, crust)
2- Moderate	Severe linear marks of skin with showing evidence of deeper skin injury (erosion, crust)
3-Severe	May erosive or crustly lesion
Lichenfication	(L)
0	None
1-Mild	Slight thickening of the skin dissemble only by touch and with skin marking minimally exaggerated
2- Moderate	Define thickening of the skin with skin marking exaggerated so that they form a Criss-cross pattern
3-Severe	Thickened indurated skin with skin marking visibly portraying an exaggerated Criss – cross pattern

Calculation of EASI Score

Head/ Neck	$E+I+Ex+Lx \text{Area} \times 0.1$	$(+ + +) \times 0.1$	
Upper limb	$E+I+Ex+Lx \text{Area} \times 0.2$	$(+ + +) \times 0.2$	
Trunk	$E+I+Ex+Lx \text{Area} \times 0.3$	$(+ + +) \times 0.3$	
Lower limb	$E+I+Ex+Lx \text{Area} \times 0.4$	$(+ + +) \times 0.4$	
EASI	Sum of all above body area		Total score

Maximum score – 70 Minimum score -0**➤ Hamilton Depression Scale**

2) Objective Criteria –

- 1] Hematological Test: Hb%, TLC, DLC, ESR.
- 2] Liver Function Test (SGOT, SGPT)

OBSERVATIONS

RESULTS

Table No. 2 – A: Showing Effect of Therapy on Subjective Parameters. (Wilcoxon Matched Pairs Single Ranked Test)

Variable	Gr.	Mean		Mean Diff.	% Relief	SD±	SE±	p value	R
		BT	AT						
<i>kaṇḍū</i>	Gr. A	2.20	1.73	0.47	21.21	0.52	0.13	0.0156	S
	Gr. B	2.13	1.73	0.40	18.75	0.51	0.13	0.0313	S
	Gr. C	1.93	1.47	0.47	24.14	0.52	0.13	0.0156	S
<i>Dāha</i>	Gr. A	1.20	0.93	0.27	22.22	0.46	0.12	0.1250	NS
	Gr. B	2.07	1.67	0.40	19.35	0.51	0.13	0.0313	S
	Gr. C	1.13	0.73	0.40	35.29	0.51	0.13	0.0313	S
<i>srāva</i>	Gr. A	1.47	0.80	0.67	45.45	0.62	0.16	0.0039	VS
	Gr. B	1.67	1.00	0.67	40.00	0.52	0.13	0.0020	VS
	Gr. C	1.80	1.07	0.73	40.74	0.46	0.12	0.0010	ES
<i>rukṣatā</i>	Gr. A	1.87	1.20	0.67	35.71	0.49	0.13	0.0020	VS
	Gr. B	2.07	1.73	0.33	16.13	0.49	0.13	0.0625	NS
	Gr. C	1.60	1.13	0.47	29.17	0.52	0.13	0.0156	S
<i>piḍakā</i>	Gr. A	1.73	1.33	0.40	23.08	0.51	0.13	0.0313	S
	Gr. B	2.00	1.53	0.47	23.33	0.52	0.13	0.0156	S
	Gr. C	2.20	1.73	0.47	21.21	0.52	0.13	0.0156	S
<i>vaivarṇya-tā</i>	Gr. A	2.07	1.53	0.53	25.81	0.52	0.13	0.0078	VS
	Gr. B	1.93	1.33	0.60	31.03	0.51	0.13	0.0039	VS
	Gr. C	2.27	1.60	0.67	29.41	0.49	0.13	0.0020	VS
<i>Rājī</i>	Gr. A	1.87	1.40	0.47	25.00	0.52	0.13	0.0156	S
	Gr. B	1.87	1.40	0.47	25.00	0.52	0.13	0.0156	S
	Gr. C	1.73	1.20	0.53	30.77	0.52	0.13	0.0078	VS
EASI Score	Gr. A	2.60	1.73	0.87	33.59	0.26	0.07	0.0001	ES
	Gr. B	2.16	1.34	0.82	37.96	0.36	0.09	0.0001	ES
	Gr. C	2.65	1.73	0.93	34.92	0.46	0.12	0.0001	ES
Hamilton D.S.	Gr. A	1.13	0.40	0.73	64.71	1.03	0.27	0.0313	S
	Gr. B	0.87	0.20	0.67	76.92	0.82	0.21	0.0156	S
	Gr. C	1.07	0.20	0.87	81.25	0.92	0.24	0.0078	VS

(NS: Non- Significant S: Significant VS: Very Significant HS: Highly Significant ES: Extremely Significant)

Table no. 3: Showing Effect of Therapy on Laboratory Parameters (Objective Parameters): (Paired 'T' Test)

Variable	Gr	Mean		Mean Diff.	% Relief	SD±	SE±	t value	P value	R
		BT	AT							
Hb%	A	12.09	12.38	0.29	2.43	1.00	0.26	1.137	0.2745	NS
	B	12.29	12.38	0.09	0.70	1.12	0.29	0.299	0.7687	NS
	C	13.11	13.15	0.04	0.31	0.66	0.17	0.235	0.8175	NS
TLC	A	8398.67	7546.67	852.00	10.14	1332.88	344.15	2.476	0.0267	S
	B	8180.00	7406.00	774.00	9.46	1224.39	316.14	2.448	0.0281	S
	C	7726.67	7203.33	523.33	6.77	810.85	209.36	2.500	0.0254	S
Neutrophil	A	62.26	62.67	0.41	0.66	5.41	1.40	0.2958	0.7717	NS
	B	62.57	63.11	0.55	0.87	7.74	2.00	0.2735	0.7885	NS
	C	57.81	56.93	0.88	1.52	6.57	1.70	0.5190	0.6118	NS
Lymphocyte	A	30.05	31.94	1.89	6.30	5.94	1.53	1.234	0.2376	NS
	B	30.89	32.89	2.00	6.48	10.96	2.83	0.706	0.4914	NS
	C	33.73	33.93	0.20	0.59	5.86	1.51	0.122	0.9043	NS
Eosinophils	A	3.83	2.21	1.62	42.26	2.34	0.60	2.682	0.0179	S
	B	3.59	2.23	1.37	38.03	2.29	0.59	2.307	0.0369	S
	C	4.71	3.13	1.58	33.52	1.74	0.45	3.515	0.0034	VS
Monocytes	A	4.01	2.86	1.15	28.74	2.18	0.56	2.049	0.0597	NS
	B	3.75	3.19	0.56	14.95	1.66	0.43	1.303	0.2136	NS
	C	3.92	3.47	0.45	11.39	0.99	0.26	1.741	0.1035	NS
Basophils	A	0.71	0.63	0.08	11.32	0.60	0.16	0.495	0.6282	NS
	B	1.24	1.17	0.07	5.91	0.60	0.16	0.472	0.6442	NS
	C	1.13	1.36	0.23	20.00	1.02	0.26	0.857	0.4059	NS
ESR	A	33.71	18.27	15.45	45.82	25.54	6.59	2.343	0.0344	S
	B	29.60	13.89	15.71	53.09	16.31	4.21	3.732	0.0022	VS
	C	23.53	14.80	8.73	37.11	11.93	3.08	2.835	0.0132	S
SGOT	A	29.04	26.01	3.03	10.45	4.86	1.25	2.418	0.0298	S
	B	31.15	27.25	3.89	12.50	6.41	1.65	2.354	0.0337	S
	C	32.97	28.03	4.94	14.98	7.36	1.90	2.621	0.0201	S
SGPT	A	27.32	25.96	1.36	4.97	7.43	1.92	0.707	0.4909	NS
	B	26.62	25.67	0.95	3.56	10.98	2.83	0.334	0.7433	NS
	C	31.97	27.00	4.98	15.57	10.14	2.62	1.901	0.0781	NS

(Hb% -Haemoglobin; TLC-Total Leucocytes Count; ESR-Erythrocyte Sedimentation Rate)

Table No. 4: Intergroup Comparison in Subjective Parameters (Kruskal Wall Test).

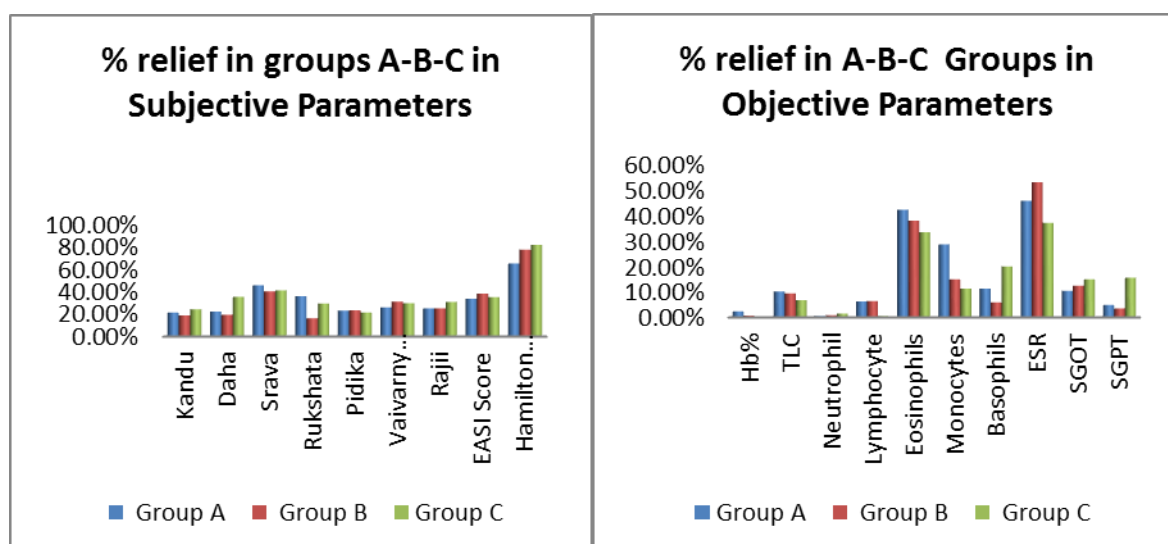
SYMPTOMS	Mean Diff Group A	Mean Diff Group B	Mean Diff Group C	KW	P	S
<i>kaṇḍū</i>	0.47	0.40	0.47	0.1760	0.9158	NS
<i>Dāha</i>	0.27	0.40	0.40	0.7586	0.6843	NS
<i>Srāva</i>	0.67	0.67	0.73	1.156	0.5611	NS
<i>rukṣatā</i>	0.67	0.33	0.47	3.304	0.1916	NS
<i>piḍakā</i>	0.40	0.47	0.47	0.1760	0.9158	NS
<i>vaivarṇyatā</i>	0.53	0.60	0.67	0.5432	0.7622	NS
<i>Rājī</i>	0.47	0.47	0.53	0.1739	0.9167	NS
EASI Score	0.87	0.82	0.93	0.6727	0.7144	NS
Hamiltone D.S.	0.73	0.67	0.83	0.4213	0.8101	NS

(NS: Non Significant)

Table No. 5: Intergroup Comparison In Lab Investigation (Objectives Parameters) (One Way Anova Test).

SYMPTOMS	Mean Diff Group A	Mean Diff Group B	Mean Diff Group C	p Value	R
HB%	0.29	0.09	0.04	0.7389	NS
TLC	852.00	774.00	523.33	0.7176	NS
Neutrophil	0.41	0.55	0.88	0.8105	NS
Lymphocyte	1.89	2.00	0.20	0.9899	NS
Eosinophils	1.62	1.37	1.58	0.9413	NS
Monocytes	1.15	0.56	0.45	0.4732	NS
Basophils	0.08	0.07	0.23	0.4491	NS
ESR	15.45	15.71	8.73	0.5202	NS
SGOT	3.03	3.89	4.94	0.7439	NS
SGPT	1.36	0.95	4.98	0.4584	NS

(NS: Non Significant)



DISCUSSION

PROBABLE MODES OF ACTIONS OF THE DRUG

As per *āyurveda*; therapeutic effect of a drug depends on pharmacodynamics properties like *rasa*, *guṇa*, *vīrya*, *vipāka* etc of that particular substance; because a drug can be able to break/reverse the pathogenesis of underlying disease. The probable mode of action of ingredients is summarized below.

Table no 6: *Arka taila*.

S. No	Properties	<i>Arka</i> ^[8]	<i>Haridrā</i> ^[9]	<i>sarsapa</i> ^[10]
1	<i>rasa</i>	<i>kaṭu, tikta</i>	<i>tikta, kaṭu</i>	<i>kaṭu, tikta</i>
2	<i>guṇa</i>	<i>Laghu, rukṣa, tīkṣṇa</i>	<i>rukṣa, laghu</i>	<i>laghu snigdha</i>
3	<i>Vīrya</i>	<i>uṣṇa</i>	<i>uṣṇa</i>	<i>uṣṇa</i>
4	<i>Vipāka</i>	<i>kaṭu</i>	<i>kaṭu</i>	<i>kaṭu</i>
5	<i>Karma</i>	<i>viṣaghna, recana dīpana, vātahara</i>	<i>viṣaghna, varṇya, kapha-vātahara, lekhaṇa</i>	<i>Vāmaka, vidāhī</i>
6	<i>doṣaghnatā</i>	<i>kapha-vātahara</i>	<i>kapha-vātahara, Pitta vardhaka</i>	<i>kapha-vātahara, Pitta vardhaka</i>

Table no 7: *viḍaṅgādi curṇa*.

S.N	Properties	<i>viḍaṅga</i> ^[11]	<i>Āmalakī</i> ^[12]	<i>Bibhitakī</i> ^[13]	<i>Haritakī</i> ^[14]	<i>Pippalī</i> ^[15]
1	<i>rasa</i>	<i>kaṭu, kaṣāya</i>	<i>lavaṇarahita paṁcarasayukt</i>	<i>kaṣāya</i>	<i>lavaṇarahita paṁcarasayukt</i>	<i>kaṭu</i>
2	<i>guṇa</i>	<i>rukṣa, laghu, tīkṣṇa</i>	<i>guru, rukṣa</i>	<i>rukṣa, laghu</i>	<i>rukṣa, Laghu</i>	<i>Snigdha, laghu, tīkṣṇa</i>
3	<i>Vīrya</i>	<i>uṣṇa</i>	<i>śīta</i>	<i>uṣṇa</i>	<i>uṣṇa</i>	<i>uṣṇa</i>
4	<i>Vipāka</i>	<i>kaṭu</i>	<i>Madhura</i>	<i>Madhura</i>	<i>Madhura</i>	<i>Madhura</i>
5	<i>Karma</i>	<i>dīpana, kṛmighnaviṣa ghna</i>	<i>vṛṣya, rasāyana, dīpana, cakṣuṣya</i>	<i>Bhedana, cakṣuṣya, keśya</i>	<i>Rasāyana, cakṣuṣya, dīpana, tridoṣahara</i>	<i>Pittakara, dīpana, vṛṣya, rasāyana</i>
6	<i>doshagnata</i>	<i>Kapha-vatahara</i>	<i>Tridosha-shamak</i>	<i>Tridosha-shamak</i>	<i>Tridosha-shamak</i>	<i>Kapha-vatahara</i>

Table no 8: Comparisons of reported Pharmacological actions.

Preparation	Drugs	Anti-Microbial Action	Anti-Inflammatory Action	Anti-Allergic Action	Immuno-Modulator Action	Hepato-protective Action	Anti-Pruritic Action	Anti-Oxidant Action
<i>Arka Taila</i>	<i>Arka</i> ^[16]	✓	-	-	-	-	-	-
	<i>Haridra</i> ^[17]	-	✓	✓	✓	✓	-	✓
	<i>Sarsapa</i> ^[18]	-	-	-	-	-	✓	-
<i>Vidang-adi Churna</i>	<i>Vidanga</i> ^[19]	✓	-	✓	-	-	-	-
	<i>Haritaki</i> ^[20]	-	✓	✓	-	-	-	✓
	<i>Bhivitaki</i> ^[21]	✓	-	-	-	-	-	-
	<i>Amalaki</i> ^[22]	-	-	-	-	✓	-	-
	<i>Pippali</i> ^[23]	✓	-	-	✓	✓	-	✓

CONCLUSION

1. Administration of *arka taila* relieves in symptoms due to its properties like *kaṭu-tikta rasa, laghu, rukṣa, tīkṣṇa, guṇa; uṣṇa vīrya, kaṭu vipāka*, and *kaphaśāmaka, kaṇḍūghna, kuṣṭhaghna* etc. This properties of drug help in reduced Vitiated *guru* and *śīta guṇa* in *vicarcikā* by counting their action.

2. Administration of *viḍamgādi curṇa* relieves in symptom due to its properties like *kaṭu-tikta, kaṣāya, rasa; laghu, rukṣa, tīkṣṇa, guṇa; uṣṇa vīrya, kaphavātaśāmaka, āmadoṣahara, kaṇḍūghna, kuṣṭhaghna* etc. help in removed vitiated *guru* and *śīta guṇa* in *vicarcikā* by counting their action.
3. Group C showed very good effect on disease comparisons to Group A and Group B, because in it internal as well as external medications were use; so it showed better result.
4. Thus it can be concluded that external application of *arka taila* and internal administration of *viḍamgādi curṇa* can be used as safe and effective therapeutic agent in the management of *vicarcikā*.

Patient Discomfort Zone

Some complained were reported by very few Patients who have taken *viḍamgādi curṇa* have loose motion and other who used *arka taila* as a local application was suffering from burning sensation on skin. But the intensity of those incidences was least.

Conflict of Interest - NIL.

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