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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF JALAUKAVACHARANA IN THE MANAGEMENT OF VATARAKTA

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ABSTRACT

Vatarakta, a condition akin to gout, is a joint disorder resulting from the imbalance of *Vata* and *Rakta Doshas* in *Ayurveda*. This study investigates the effectiveness of *Jalaukavacharana* (leech therapy) combined with *Shatavari Chhinnruhadi Kashaya* in managing *Vatarakta.* Thirty patients diagnosed with *Vatarakta* at the National Institute of Ayurveda, Jaipur, were divided into two groups: Group A received *Jalaukavacharana* and *Shatavari Chhinnruhadi Kashaya. In contrast,* Group B received only the *Shatavari Chhinnruhadi Kashaya*. Both groups had significant relief in symptoms like pain, swelling and tenderness. In Group A, there was more significant relief than in Group B. While both groups showed significant reductions in ESR, changes in serum uric acid levels were insignificant. This suggests that *Ayurvedic* therapies may primarily aid in symptom management rather than uric acid reduction. This study concludes that combining *Jalaukavacharana* with herbal therapy offers a holistic approach to managing *Vatarakta.*

Keywords: *Vatarakta, Jalaukavacharana, Shatavari Chhinnruhadi Kashaya,*

INTRODUCTION

Gout is the most common form of inflammatory arthritis, manifesting as acute flares of severe joint pain, swelling, redness, and warmth in one or more joints, which can progress to chronic destructive ar-

thropathy.[1] The prevalence of gout ranged from 1–4% worldwide, and incidence ranged from 0.1–0.3%. Gout is more common in men vs. women by 3:1 to 10:1. Gout incidence and prevalence increased by each decade of life, with prevalence rising to 11–13% and incidence increasing to 0.4% in people older than 80.[2] Symptoms of gout are similar to symptoms of *Vatarakta*. In *Ayurveda, Acharyas* mentioned *Ruk*(pain), *Daha*(burning sensation), *Shotha*(swelling) and *Raktavarnata*(redness). According to *Acharya Sushruta*, the aggravation of *Vatarakta* occurs in individuals who indulge in *Mithya Ahara Vihara* (incorrect diet and lifestyle practices) and who possess a constitution that is *Sukumara*(tender), *Sthula*(obese) and *Sukhi*(tranquil).[3] *Vata* and *Rakta* can spread throughout the body due to their properties like *Sukshmatva* (minuteness*), Saratva* (spreading nature), and *Dravatva* (liquidity).[4] Various factors such as excessive riding, carrying heavy weights, excessive sexual intercourse, drinking large quantities of wine, and overindulgence in foods that are *Ushna* in *Virya* (hot in potency) can lead to the vitiation of *Vata* and *Rakta.*[5] The aggravated *Vata* is trapped by the vitiated *Rakta,* leading to further vitiation of *Vata,* which aggravates *Rakta.* When the vitiated *Vata* and *Rakta reach Sandhi,* pathological changes occur, which are the sites of *Kapha*. The accumulated *Vata* and *Rakta* and *Pitta* and *Kapha* produce joint pain and swelling.[6] Deformities may also appear in the later stages of the disease. Ayurveda advocates various promotive, preventive, and curative measures in this context. It describes *Sadvritta* (ethical conduct), *Swasthavritta* (principles of healthy living), *Ahara-Vihara* (diet and lifestyle), and unique therapeutics such as *Aushadhi* (medicines) based on the doctrines of *Samshodhana (*purification) and *Samshamana* (pacification). In this present study, *Jalaukavcharana* was selected as a Shodhana Chikitsa, as mentioned in *Vatarakta Chikitsa* in *Charaka Chikitsa Sthana. Jalaukavacharana* has been indicated for bloodletting in *Vatarakta, where* pain, burning and redness are found[7]. In *Sahasrayogam, Shatavari Chhinnruhadi Kashaya* is indicated as *Vataraktahara Kashaya,* along with *Madhuyasti Churna*[8]. The ingredients of this formulation are *Shatavari, Guduchi, Bala, Amalaki, and Ikshu*. Both *Guduchi* and *Bala* are traditionally used. Therefore, formulations like *Shatavari Chhinnruhadi Kashaya* have been chosen as *Shamana* (pacifying) formulations for this study. This study aims to evaluate the efficacy of *Jalaukavacharana* with and without *Shatavari Chhinnruhadi Kashaya*.

Materials and methods

This was a single-centric, prospective, parallel-group clinical trial on 30 patients of *Vatarakta*. Ethical clearance was obtained from the institutional ethical committee, NIA, Jaipur, before commencing trial no. IEC/ACA/2022/02/80, dated 10/10/2022. This study was registered under the CTRI, REF/2023/06/068364. The registration number for this trial is CTRI/2023/06/054036. This clinical trial was initiated after the written consent of the patients.

Selection of drugs

Shatavari Chhinnruhadi Kashaya was chosen as a *Shamana Yoga* and *Jalaukavacharana* as a *Samshodhana Karma* for this trial.

Preparation of drugs

Shatavari Chhinnruhadi Kashaya was prepared in *Rasayanashala* of National Institute of Ayurveda Jaipur. For this, *Kwatha* and *Ikshu Kanda* were bought from the market, and *Shatavari Moola, Guduchi* Stem, *Bala Moola*, and *Amalaki Twak* were taken from *Rasayanashala* in equal proportions. *Yastimadhu Churna* was also prepared from *Rasayanashala*, NIA Jaipur.

Dosage

Shatavari Chhinnruhadi Kashaya was given orally in a dose of 1 *Pala*(48ml) twice a day on an empty stomach, and *Jalaukavacharana* was done once a week for three consecutive weeks.

Inclusion criteria

1. Patients having classical symptoms of *Vatarakta*
2. Age group between 20 to 60 years.
3. Patient with normal bleeding time and clotting time.

Exclusion criteria:

1. Patients have other systemic illnesses like diabetes mellitus or hypothyroidism.

2. Patients having any other systemic diseases such as paralysis, Parkinson's disease, severe anaemia, cancer patients, etc.
3. Pregnant women.

Withdrawal criteria:

The participant might be withdrawn from the trial if-

1. They develop any severe condition or adverse effect (necessitating hospitalization).
2. The patient wants to withdraw from the clinical trial due to any reason

Sampling technique

Patients fulfilling the inclusion criteria were selected, and a simple random sampling technique was used to group the patients into two groups.

Selection of patients

The patients approaching the outpatient department(OPD), National Institute of Ayurveda Hospital, Jaipur, with the clinical signs and symptoms of *Vatarakta* as per *Ayurveda* literature.

Criteria for diagnosis

For correct diagnosis and assessment, a case record proforma was prepared to incorporate all the signs and symptoms of the disease and the *Dosha, Dushya,* etc., based on the proforma.

Interventional phase

The prescribed drug and procedure intervened in the clinical study. This phase covers the following points:-

- Grouping:- All the patients were divided into two groups(Group A and Group B) to compare the efficacy of *Jalaukavacharana* with and without *Shamana Yoga*.
- Group A:- 15 patients were treated with *Shatavari Chhinnruhadi Kashaya* and *Jalaukavacharana.*
- Group B: Only 15 patients were treated with *Shatavari Chhinnruhadi Kashaya*.

Assessment criteria

Subjective criteria

Subjective criteria were signs and symptoms mentioned in the *Ayurveda* text for *Vatarakta.* Cardinal symptoms were *Toda(*pain), *Sotha(*swelling*), Daha(*burning sensation*),* and *Sparsha Shishnuta(*tenderness*).* General symptoms were *Kandu(*itching*),* *Guruta(*heaviness), *Anga-Graha*(stiffness*),* *Sitata*(cold sensation*),* *Sandhi Shaithilya(*joint laxity*),* and *Twak Vaivarnya(*skin discolouration).

Objective criteria

The objective criteria were changes in laboratory investigation: ESR and S.uric acid.

Scoring

Table no.1 -Showing scoring parameters of swelling, tenderness and burning sensation

1. Pain:- VAS (visual analogue scale) used for pain assessment					
Parameter	No pain	Mild pain(bearable, comes occasionally, no difficulty in joint movement))	Moderate pain(difficulty in joint movement, requires medications)	Severe pain(more difficulty in joint movements; pain disturbs sleep and requires strong analgesics)	
Score	0	1	2	3	
2. Swelling- Assessed with the circumferential variation on comparison with the circumference of normal & same joint of the other side.					
Parameters	No swelling	Circumferential Variation of 0-5mm	Circumferential Variation of 5-10mm	Circumferential Variation of 10-15mm	Circumferential Variation of 15-20mm
Score	0	1	2	3	4
3. Tenderness:- Based on Ritchie index					
Parameters	No tender-	Tender	Tender and Winces	Tender, Winces and	

	ness			Withdraw	
Score	0	1	2	3	
4. Burning sensation- VAS (visual analogue scale)					
Parameters	No Burning sensation	Burning not disturbing daily routine	Burning, which requires analgesic with efficient control	Burning, which requires analgesic with poor control	Burning is not responding to analgesic
Score	0	1	2	3	4

Statistical analysis:

All the results were calculated by using graph pad prism 10.

Intra-group comparison: The Wilcoxon test was used for non-parametric data, and a paired t-test was used for parametric data.

Inter group comparison- for non -parametric data, Mann Whitney test was used. For parametric data, an unpaired t-test was used.

Observations and results

Table no.2- Showing intra-group results a comparison of symptoms and lab. investigations

Symptom	Group	Mean		Difference	%improvement percentage	SD	SE	W	P	Significance
		BT	AT							
Cardinal symptoms										
Toda(Pain)	A	2.8	0.67	2.13	76.07	0.5164	0.1333	120	<0.0001	HS
	B	2.6	0.867	1.733	66.53	0.7037	0.1817	120	<0.0001	HS
(*Shotha*)Swelling	A	2.6	0.47	2.13	81.92	0.7432	0.1919	120	<0.0001	HS
	B	2.067	0.533	1.533	74.4	0.8338	0.2153	120	<0.0001	HS
Daha(burning sensation)	A	2.8	0.6	2.2	78.57	1.014	0.2619	105	0.0001	HS
	B	3	0.933	2.067	68.9	0.5936	0.1533	120	<0.0001	HS
Sparshasahishanuta(Tenderness)	A	2.4	0.53	1.867	77.92	0.5164	0.1333	120	<.0001	HS
	B	2.6	0.733	1.867	71.92	0.3519	0.0908	120	<0.0001	HS
Stiffness	A	2.33	0.53	1.8	77.25	0.414	0.1069	120	<0.0001	HS
	B	2	0.667	1.333	66.5	0.488	0.126	120	<0.0001	HS
Kandu	A	1	0.33	0.67	67	0.488	0.126	55	0.002	S
	B	0.67	0	0.667	67	0.8165	0.2108	36	0.0078	S
General symptoms										
Sitata	A	0.2667	0.133	0.133	50.19	0.3519	0.0908	3	0.5	NS
	B	0.1333	0.067	0.067	50.26	0.2582	0.067	1	>0.9999	NS
Twak vaivarnya	A	0.2	0	0.2	100	0.414	0.107	6	0.25	NS
	B	0.2	0.133	0.067	33.5	0.2582	0.067	1	>0.9999	NS
Guruta	A	0.3333	0.2	0.133	40.03	0.3519	0.091	3	0.5	NS
	B	0.1333	0.067	0.067	50.26	0.2582	0.067	1	>0.9999	NS

Sandhi Saithilya	A	0.2667	0.067	0.2	74.91	0.414	0.107	6	0.25	NS
	B	0.1333	0.067	0.067	49.62	0.2582	0.067	1	>0.9999	NS
Objectives parameters										
ESR	A	30.13	19.8	10.33	34.28	9.612	2.482	4.16	0.001	S
	B	43.67	29.6	14.07	33.66	16.54	4.271	3.29	0.005	S
Sr.uric acid	A	4.94	4.42	0.52	10.52	1.031	0.266	1.95	0.071	NS
	B	3.983	3.923	0.05	1.25	0.5422	0.14	.36	0.726	NS

AT= after treatment, BT= before treatment, ESR= erythrocyte sedimentation rate, HS= highly significant, NS= not significant, p=p value, S=significant, SD= standard deviation, SE= standard error, W= wilcoxon test,

Table no. 3 shows the inter-group results of a comparison of symptoms and lab results. investigations

Symptom	N	Group	Mean Difference	SD	SE	U	P	Significance
Toda(Pain)	15	A	.8667	0.64	0.1652	95	.5225	NS
		B	.6667	0.49	0.1260			
Shotha(Swelling)	15	A	.5333	0.92	0.236	104.5	.7104	NS
		B	.4667	0.516	0.133			
Daha(Burning sensation)	15	A	.9333	.5936	0.1533	81	.1961	NS
		B	.6000	.5071	0.1309			
Sparshasahishnuta(Tenderness)	15	A	1.867	0.516	0.1333	97	.5547	NS
		B	1.867	0.352	0.0908			
Stiffness	15	A	.6667	0.488	0.1260	97.50	.7104	NS
		B	.5333	0.516	0.1333			
Kandu	15	A	.3333	0.488	0.126	75	.0421	S
		B	0.000	0.000	0.000			
Sitata	15	A	0.1333	0.352	0.0909	105	>0.999	NS
		B	0.0667	0.258	0.0666			
Twak Vaivarnya	15	A	0.2	0.414	0.1069	97.5	.4828	NS
		B	0.0667	0.258	0.0667			
Guruta	15	A	0.1333	0.352	0.0908	97.5	0.5977	NS
		B	0.06667	0.258	0.0667			
Sandhi Saithilya	15	A	0.2	0.414	0.1069	112.5	>0.999	NS
		B	0.06667	0.258	0.0667			
Parametric data unpaired t-test								
ESR	15	A	29.60	13.08	3.376	64.5	.0464	S
		B	19.80	12.14	3.134			
Sr. uric acid	15	A	3.933	1.363	0.3518	1.95	.2299	NS
		B	4.420	0.708	0.1829			

AT= after treatment, BT= before treatment, ESR= erythrocyte sedimentation rate, N=number of patients, NS= not significant, S=significant, SD= standard deviation, SE= standard error, p=p value U=Mann Whitney test

Intra-group comparison (Table no 2)

- Effect of *Jalaukavacharana* along with *Shatavari Chhinnruhadi Kashaya* in group A, were found highly significant($p<.001$) in cardinal symptoms *Toda*, *Daha*, *Sotha*, *Sparshasahishnuta*, in general symptoms, in stiffness it found highly significant, in *Kandu* it found significant($p<0.05$), in *Guruta*, *Sitata*, *Sandhi Shaithilya*, *Twak Vaivarnya* it found not significant($p>0.05$). In the objective parameter, in ESR, it was found to be signif-

icant, and in serum uric acid level, it was found not significant.

- Effect of *Shatavari Chhinnruhadi Kashaya* in group B were found highly significant($p<.001$) in cardinal symptoms *Toda, Daha, Sotha, Sparshasahishnuta*, in general symptoms, in stiffness it found highly significant, in *Kandu* it found significant($p<0.05$), in *Guruta, Sitata, Sandhi Shaithilya, Twak Vaivarnya* it found not significant($p>0.05$).). In the objective parameter, in ESR, it was found to be significant, and in serum uric acid level, it was found not significant.

Intergroup comparison

From Table 3, it is clear that there was a statistically significant difference ($p<0.05$) in the effect of therapy in group A and group B on *Kandu* and ESR. Although in *Toda, Daha, Sotha, Sparshasahishnuta, Sitata, Guruta, Stabdhata, Sandhi Shaithilya, Twak Vaivarnya*, and serum uric acid level, no statistical difference($p>0.05$) was observed in the effect of therapies of group A and group B.

- *Toda* (Joint Pain):- The relief observed in both Group A (*Jalaukavacharana* along with *Shatavari Chhinnruhadi Kashaya*) and Group B (*Shatavari Chhinnruhadi Kashaya*) for *Toda* was statistically highly significant. Group A experienced a 76.07% reduction in pain, while Group B showed a 66.53% reduction. This indicates that the combination therapy in Group A provided greater relief in joint pain compared to Group B.
- *Shotha* (Swelling):-Both groups showed statistically significant improvement in swelling. Group A had an 81.92% reduction in *Shotha,* while Group B showed a 74.4% reduction. This suggests that *Jalaukavacharana* combined with *Shatavari Chhinnruhadi Kashaya* is more effective in reducing swelling than the *Kashaya* alone.
- *Daha* (Burning Sensation):- Group A and Group B demonstrated a statistically significant decrease in burning sensation. Group A showed a 78.57% reduction, compared to 68.9% in Group B. The superior relief in Group A can be attributed to the correction of *Margavarodha* and the elimination of *Dushita Rakta* through *Jalaukavacharana*, along with the blood-purifying and *Pittashamaka* properties of the herbal drugs.
- Tenderness (*Sparshasahishnuta):-* Statistically significant relief in tenderness was observed in both groups. Group A showed a 77.92% improvement, while Group B showed a 71.92% improvement, with Group A demonstrating a slightly higher effectiveness in reducing tenderness.
- *Stabdhata* (Stiffness):- The relief from stiffness was statistically highly significant in both groups. Group A (*Jalaukavacharana* along with *Shatavari Chhinnruhadi Kashaya*) experienced a 77.25% reduction in stiffness, while Group B (*Shatavari Chhinnruhadi Kashaya)* showed a 66.5% reduction. This indicates that the combination therapy in Group A provided greater relief from stiffness.
- *Kandu* (Itching):- Both groups showed statistically significant relief from itching, with an equal reduction of 67% in both Group A and Group B.
- *Sitata* (Cold Sensation):- The reduction in *Sitata* was statistically insignificant in both groups. Group A showed a 50.19% reduction, while Group B had a similar result at 50.26%.
- *Twak Vaivarnya* (Skin Discoloration):-The relief from skin discolouration was statistically insignificant in Group A and Group B.
- *Guruta* (Heaviness):- Both groups experienced statistically insignificant relief from the symptom of heaviness. Group A showed a 40.03% reduction, while Group B showed a 50.26% reduction.
- *Sandhi Shaithilya*:- The relief from joint laxity was statistically insignificant in both Group A and Group B.
- ESR (Erythrocyte Sedimentation Rate):- Group A showed a significant 10.33% reduction in ESR, while Group B exhibited a slightly higher reduction of 14.07%. The greater decrease in Group B may be due to the reduced levels of circulating local inflammatory mediators and the effects of the *Shaman* therapy.
- Serum Uric Acid:- In Group A, the reduction in serum uric acid was 10.52%, but this was statistically insignificant. Similarly, Group B showed a

1.25% reduction, which was also statistically insignificant.

Comparison of the effect of therapy on intergroup:-

On comparing the results of two groups based on *Toda, Daha, Sotha, Sparshasahishnuta, Kandu, Stabdhata, Guruta, and Sitata. Twak Vaivarnya, Sandhi Shaithilya*, ESR, serum uric acid, it was observed that *Jalaukavacharana* along with *Shatavari Chhinnruhadi Kashaya,* gave more relief as compared to only *Shatavari Chhinnruhadi Kashaya*. There was a statistically significant difference ($p<0.05$) in the effect of therapies in group A and group B on *Kandu* and ESR.

DISCUSSION

Vatarakta is a systemic, inflammatory disease primarily targeting smaller and larger joints. In advanced stages, it can lead to deformities in the affected structures and impair their functions. Common symptoms include *Ruka*(pain), *Shotha*(swelling), *Daha*(burning sensation), and *Sparshasahishnuta*(tenderness). *Vata* and *Rakta* are the key factors believed to contribute to the onset of *Vatarakta*. For this study, *Shatavari Chhinnruhadi Kashaya* and *Jalaukavacharana* were selected for treatment. Ingredients of *Shaman Kashaya* have *Vedanasthapana, Raktapitta shamana, Vatapitta shamak,* and *Shothahara* properties.

Probable Mode of Action of *Jalaukavacharana*

Jalaukavacharana, a procedure used to eliminate *Raktadushti* (vitiated blood), is effective in preventing diseases and complications caused by the vitiation of *Rakta*. According to the *Sushruta Samhita*, this procedure is particularly recommended for conditions like *Vatarakta* in *Ayurveda*. It is believed that *Jalaukavacharana* works by removing *Dushita Rakta* from the body, thus clearing the obstruction in the pathways of *Vata. Chakrapani* explains that this process removes the *Avarana* (obstruction) of *Vata,* allowing it to flow normally.[9]

Jalaukavacharana is also indicated to relieve *Toda*(pain) and reduce *Shotha* (swelling) and *Daha*. It effectively addresses symptoms such as pricking pain *(Toda),* swelling (*Shotha*), and tenderness (*Sparshasahishnuta).*[10] *Vagbhata* further adds that by removing *Dushita Rakta,* redness and pain are rapidly relieved.[11]

Probable Mode of Action of *Shaman Yoga*

As described in the drug review, *Shatavari Chhinnruhadi Kashaya* is effective in treating *Vatarakta* due to the combined properties of its ingredients. *Shatavari* possesses *Shothahara* (anti-swelling) and *Vatapittashamaka* properties.[12] *Guduchi* has *Pittashamaka Vataraktahara* and *Tridoshaghna* effects. *Amalaki* has *Vatapittashamaka, Vedanasthapana*, [13] and *Rakta pittashamaka* properties,[14] while *Bala* and *Ikshu* are known for their *Vatanashaka* and *Raktapitta shamaka* effects.[15,16] *Yastimadhu* is similarly effective in balancing *Vata* and *Pitta.*[17] Their *Vedana Shamaka* (pain-relieving), *Vata Shamaka* (balancing *Vata*), *Rasayana* (rejuvenating), and *Pachana* (digestive) properties are beneficial in disrupting the pathogenesis (*Samprapti*) of *Vatarakta*.

This formulation is beneficial for treating *Vatarakta* due to its *Raktashodhak* and *Raktapitta shamaka* properties, which help alleviate *Daha.* Its *Shothahara* (anti-inflammatory) action helps reduce swelling, which is common in *Vatarakta* due to the inflammatory response. Additionally, its *Vatashamak* and *Vedanashamak* effects contribute to relieving pain.[18]

Guduchi contains active compounds such as tinosporin, cordiolite, tinosporide, corditol, tinosporic acid, and tinosporol. It is known for its antirheumatic and anti-inflammatory properties, with studies showing that its anti-inflammatory action is similar to that of nonsteroidal anti-inflammatory drugs (NSAIDs). Research on induced oedema, arthritis, and human arthritis has confirmed its significant anti-inflammatory effects.[19]

CONCLUSION

Based on a comprehensive analysis of the findings, the following conclusions have been drawn:

1. In group A, treated with *Jalaukavacharana* (leech therapy) along with *Shamana Yoga*, and group B, treated with only *Shamana Yoga*, significant improvement was observed in most of the primary and

general symptoms of *Vatarakta*. However, there was no notable reduction in serum uric acid levels or ESR.

2. Statistically significant relief was noted in symptoms such as burning sensation (*Daha*), tenderness (*Sparsha Sahishnuta*), pain (*Toda),* and swelling in both groups, with a higher percentage of improvement in group A receiving *Jalaukavacharana* with *Shamana Yoga.*

3. *Shatavari Chhinnruhadi Kashaya,* an herbal decoction, effectively managed the symptoms of *Vatarakta*, demonstrating its therapeutic potential.

4. A comparison of the two therapies indicates that *Jalaukavacharana* combined with *Shamana Yoga* provides superior relief in most symptoms of the disease compared to *Shamana Yoga* alone.

In conclusion, the combination of *Jalaukavacharana* and *Shamana Yoga,* followed by the long-term use of *Shamana* drugs, may offer a more effective treatment approach for managing *Vatarakta.*

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