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A COMPARATIVE CONTROL CLINICAL STUDY OF *BODHIVRIKSHA KASHYA GHANA VATI* IN THE CASES OF *VATARAKTA* VIS-À-VIS GOUT

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ABSTRACT

Gout is metabolic disorder an inflammatory response caused by the buildup of monosodium urate crystals within the joints. This crystal deposition is due to increased uric acid levels in the body. The condition is marked by recurring episodes of intense pain, swelling, and limited joint mobility, significantly affecting the quality of life. In recent years, the prevalence of gout has been on the rise.Based on its etiological and clinical aspects, the Ayurvedic condition known as '*Vatashonita* (VS) or *Vatarakta* (VR)' closely parallels gout and hyperuricemia described in modern biomedical science. *Vatarakta* is identified as a disorder caused by the simultaneous aggravation of *Vata* and *Rakta*. In this condition, the *VataDosha* becomes obstructed due to the increased severity of *RaktaDosha*. Although it primarily manifests as a *Vata*-dominant disorder, it involves the imbalance of all three doshas, with *Rakta* being the primary dhatu affected.

Keywords: Ayurveda, Gout, Hyperuricemia, *Vatarakta*.

Aim - To perform a Comparative control clinical study of *Bodhivriksha Kashaya Ghana Vati* in the cases of *Vatarakta* vis-à-vis Gout.

Method - All the references from Ayurvedic and Modern scripture, researches and journals are assessed prior to compilation of article.

INTRODUCTION

Gout is a metabolic disorder linked to purine metabolism, characterized by an inflammatory response to monosodium urate monohydrate (MSUM) crystals.[i] These crystals develop as a result of hyperuricemia, a condition in which uric acid levels in the blood become excessively high. Historically, gout has been called "the disease of kings" or "rich man's disease," highlighting its association with wealthier individuals, likely due to dietary habits and lifestyles that promote high uric acid levels.[ii] Similarly, Ayurvedic texts describe this condition with the phrase "***Prayahsukumaranam, mithya-aharvirharinam***," implying its occurrence in those who lead a luxurious lifestyle and consume improper diets.

Gout arises from a complex interplay of genetic predisposition and environmental influences that either reduce uric acid excretion or increase its production. A key factor in the onset of gout is the elevation of serum uric acid levels beyond a critical threshold, which facilitates the crystallization of uric acid.[iii] Globally, the prevalence of gout varies between 0.1% and 10%, while the incidence rate ranges from 0.3 to 6 new cases per 1,000 person-years.[iv]

The causative factors, pathological processes, and clinical presentation of gouty arthritis closely align with the Ayurvedic condition known as *Vatarakta*. This disorder is characterized by the sudden onset of severe joint pain, initially affecting the joints of the feet, hands, and their roots, with the pain spreading to other joints in a manner resembling a rat bite (*Akhuvisha*).[v] In *Vatarakta*, the obstruction of *Vata* Dosha by vitiated *Rakta* Dosha results in heightened virulence of *Vata*, leading to a disorder of *Rakta* Dhatu.[vi]*Vatarakta* is described in Ayurveda by various names, including *Vatashonita*, *Khuddavata*, *Vatabalasaka*, *Aadhyavata*, and *Vataasrika*.[vii]

In modern medical practice, gouty arthritis symptoms are commonly managed with uricosuric drugs, xanthine oxidase inhibitors, NSAIDs, and glucocorticoids. However, these treatments are often associated with a broad range of adverse effects, including renal insufficiency and gastrointestinal complications. Long-term use of these medications can exacerbate the chronic nature of the disease. Therefore, there is an evident need for more effective and sustainable treatment options. Ayurveda offers significant potential in managing such conditions, with its holistic approach focusing on the root causes, balancing doshas, and promoting overall well-being.

Material and Methods

Trial design

This study was an open labelled, randomized and controlled clinical trial.

Study was conducted on 100 willing participants on randomly basis and they were divided into two groups. One group of patients received *Ayurvedic* trial drug as intervention, whereas another group received conventional allopathic treatment as control drug. Total duration of treatment was 12 weeks for both the groups with the three follow ups of one month interval.The study was approved by the Institutional Ethical Committee (reference number **Dean/2022/EC/4005.**). The trial was also registered in the Clinical Trials Registry of India (**CTRI/2023/05/053250**). Written informed consent was taken from the patients for both the groups prior to their enrolment. The selected patients were randomly allocated in both the groups through computer-generated methods.

Aims and objectives

The aim of the present study was to evaluate the effectiveness and safety of *Bodhivriksha Kashaya Ghana Vati* and Febuxostat on subjective & objective parameters in the cases of *Vatarakta* vis-à-vis Gout, assessment of status of Ama before and after treatment, compare the efficacy of trial drug with parallel control drug (i.e., febuxostat), and evaluate the quality of life (QoL) in case of gout before and after treatment.

Inclusion criteria

1) Patients willing to participate in the trial.
2) Patients fulfilling the 2015 ACR/EULAR Gout classification criteria and classical. signs and symptoms mentioned.
3) Patients between the age group of 25-55 years of either sex.
4) Patients having serum uric acid >7mg/dl in males and >6mg/dl in females with or any associate features like joint pain and Inflammation.

Exclusion criteria

- Patients unwilling to participate in the trial.
- Patients below the age of 25 years and above 55 years of age.
- Patients- suffering from chronic respiratory, cardiac, hepatic and hormonal disorder.
- Mentally unstable and substance abuse patients
- Patients of Chronic Vatarakta who have developed gross joint deformity and associated with complication.
- Pregnant and lactating women
- Patients about to undergo surgical intervention

Termination criteria

- Sudden deterioration in patient's health status during the period of study.
- Noncompliance of the trial drug

Diagnostic criteria

A person can be considered for Gout when the patient has 2015 ACR/EULAR Gout classification criteria Score≥8.

Parameters for the assessment of therapeutic response

Subjective parameters

Objective parameters

Study design and treatment schedule

It was a randomized open parallel control clinical trial. The selected patients were enrolled on "first come first serve" basis and then randomly allocated into two groups based on computer-generated random allocation sequence 1:1 was the ratio to divide the patients into Ayurvedic trial and control groups. A total of 100 cases (fulfilling the diagnostic as well as inclusion and exclusion criteria) were enrolled for the clinical trial.

1. Ayurveda treated Group- A (Number of Cases-50): Treated with Ayurvedic formulation-*Bodhivriksha kashaya Ghana Vati 500 mg*- 2BD with plain water.
2. Modern Treated Group- B (Number of Cases-50): Treated with modern drug-Febuxostat 40mg- 1OD after meal with plain water

During the course of the trial period, no additional dietary and lifestyle interventions were enforced.

Follow-up

The duration of treatment was 3 months with follow-up at 30 days interval. For each follow–up, the patients were assessed for Serum Uric acid, CRP, ESR, while complete blood count, renal function test, liver function test, status of Ama, and QoL were assessed before and after the completion of trial treatment.

Intervention

One Ayurvedic drug and one conventional (Febuxostat) drug were used in this research work. *Bodhivriksha kashaya Ghana Vati* of Ayurveda were selected as trial drugs.[Table 1]

Results

Clinical symptomatology

At the time of registration of patients, it was found that the incidence of Sandhishoola was observed in 100% patients, Sandhishotha in 56.4% patients, Sandhistambha in 65.9% patients, Sparshasahyaha in 87.9% patients, Daha in 93.4% patients, Twak Vaivarnya in 29.6% patients, Visphota in 0% patients, Sandhi Vikriti in 5.4% patients in 91 cases enrolled of Gout. This result indicates that clinical presentation of gout can be atypical and presence of all the signs and symptoms at a time is not mandatory to diagnosis the cases of gout.[Table 2]

Table 1: Description of drugs

Name of drug	Latin/scientific name	Family	Part	Formulation
Bodhivriksha	*Ficus religiosa linn*	Moraceace	Bark	*Ghana Vati*

Table 2: Incidence of clinical symptomatology in 91 cases of Gout

Clinical Features	Total number/% of clinical symptoms at BT	
	Number	Percentage
Sandhishoola (Joint pain)	91	100%
Sandhishotha (Swelling)	57	56.04%
Sandhistambha (Stiffness)	60	65.9%
Sparshasahyaha (Tenderness)	80	87.9%
Daha (Burning sensation)	85	93.4%
Twak Vaivarnya (Discoloration of skin)	27	29.6%
Visphota (Desquamation)	0	0%
Sandhi Vikriti (Deformed joint)	5	5.4%

DISCUSSION

The silent features of this study are summarized below:

Among 100 patients, 91 patients have completed three follow ups of one month interval for a period of 3 months. Total 9 patients had been dropped out from the study. In which 3 and 6 patients quit from Group A and Group B respectively due to some of their personal problems and family constraints. The complete data of the present study put over SPSS software and the clinical outcome of observations & result, discussion and summary & conclusion have been drawn

Table.3 Showing Percentage of Improvement in Different symptoms of Gout after trial intervention

Clinical Features	Total number/percentage of clinical symptoms at BT		Remained number/percentage of clinical symptoms at AT		Percentage of Improvement	
	Group A	Group B	Group A	Group B	Group A	Group B
Sandhishoola **(Joint pain)**	47 100%	44 100%	13 27.6%	6 13.63 %	34 72.4%	38 86.3%
Sandhishotha **(Swelling)**	30 63.8%	27 61.36%	5 10.6%	0 0%	25 53.2%	27 61.3%
Sandhistambha **(Stiffness)**	27 57.4%	24 54.4%	3 6.3%	0 0%	24 51.1%	24 54.4%
Sparshasahyaha **(Tenderness)**	47 100%	44 100%	7 14.8%	6 13.6%	40 85.2%	38 86.4%
Daha **(Burning sensation)**	44 93.6%	42 94.5%	3 6.3%	0 0%	41 87.3%	42 94.5%
TwakVaivarnya **(Discoloration of skin)**	16 34.0%	11 25%	1 2.2%	0 0%	15 31.8%	11 25%
Visphota **(Desquamation)**	0 0%	0 0%	0 0%	0 0%	0 0%	0 0.0%
SandhiVikriti **(Deformed joint)**	2 4.25%	3 6.81%	2 4.25%	2 4.5%	0 0%	1 2.27%

In group A, before treatment, 47(100%) patients had symptoms of *Sandhishoola*. After trial treatment, 13(27.6%) patients have no response with the symptoms of *Sandhishoola*, while 34(72.4%) patients responded with *Bodhivriksha* treated group. In group B, before treatment, 44(100%) patients had symptoms of *Sandhishoola*. After trial treatment, 6(13.63%) patients have no response with the symptoms of *Sandhishoola*, while 38(86.3%) patients responded with modern treated group.

In group A, before treatment, 30(63.8%) patients had symptoms of *Sandhishotha*. After trial treatment, 5(10.6%) patients have no response to the treatment with the symptoms of *Sandhishotha*. While 25(53.2%) patients responded with *Bodhivriksha* treated group. In group B, before treatment, 27(61.36%) patients had symptoms of *Sandhishotha*. After trail treatment, no patients have symptoms of *Sandhishotha*, while 27(61.36%) patients responded with modern treated group.

In group A, before treatment, 27(57.4%) patients had symptoms of *Sandhistambha*. After trail treatment, 3(6.3%) patients have no response with symptoms of *Sandhistambha*, while 24(51.1%) responded with *Bodhivriksha* treated group. In group B, before trail treatment, 24(54.4%) patients had symptoms of *Sandhistambha*. After treatment, no (0.0%) patients have symptoms of *Sandhistambha*, while 24(54.4%) responded with modern treated group.

In group A, before treatment, 44(93.6%) patients had symptoms of *Daha*. After trail treatment, 3(6.3%) patients have no response in the symptoms of *Daha*. While 41(87.3%) patients have symptoms of *Daha*. In group B, before treatment, 42(94.5%) patients had symptoms of *Daha*. After trail treatment, no patients 0(0%) have symptoms of *Daha*, while 42(94.5%) patients responded with modern treated group.

In group A, before treatment, 47(63.8%) patients had symptoms of *Sparshasahyaha*. After trail treatment,7(14.8%) patients have no response in symptoms of *Sparshasahyaha*, while 40(85.2%) responded with *Bodhivriksha* treated group. In group B, before treatment, 44(100%) patients had symptoms of *Sparshasahyaha*. After trail treatment, 6(13.6%) patients have no response symptoms of *Sparshasahyaha*. While 38(86.4%) responded to the modern treated group.

In group A, before treatment, 16(34%) patients had symptoms of *Twak Vaivarnya*. After trial treatment, 1(2.2%) have no response in the symptoms of *Twak Vaivarnya*, while 15 (31.8%) patients of group A responded well with *Bodhivriksha* intervention in *Twak Vaivarnya*. In group

B, before treatment, 11(25%) patients had symptoms of *Twak Vaivarnya*. After trial treatment, 11 (25%) responded well after modern drug intervention.

In group A, before treatment, 2(4.5%) patients had symptoms of *Sandhi Vikriti*. After trial treatment, it remained same to 2(4.5%) patients. The percentage of improvement in Group A was 0%. In group B, before treatment, 3(6.81%) patients had symptoms of *Sandhi Vikriti*. After trial treatment, 2(4.5%) patients remained as such, while 1 (2.22%) patient responded after control treatment intervention.

In this study, it was observed that a maximum 51(51%) patients belonged to the age group of 45-55 years followed by 41 (41%) patients in the age group of 35-44 years.[viii]Majority of patients were belonged to Hindu religion i.e., 96%. Sex-wise observation reveals that a maximum of 76% of patients were male[ix]. The study revealed that the majority of the patients belonged to the middle class (92%). It was found that 56% patient had positive family history[x]. and59(59%) of the patients had reduced appetite, In this study it is observed that 52% had constipated bowel habits, and dietary habits reveals that 57(57%) patients are of mixed by diet[xi], it was found that maximum number of patients were of *Vata-pradhana prakriti* (57%), and *Rajasika* (71%) in nature, maximum number of patients had *Madhyama Abhyavarana shakti* (average capacity to ingest food) and *Madhyama Jarana Shakti* (average capacity to digest food) 63% and 69% respectively.

The total score of ACR EULAR CRITERIA 2015shows that the initial mean and SD in Group-A was 8.68±0.862 after 3 months of trial treatment it was shifted to 6.85±1.335. The improvement was statistically highly significant (p= 0.000). In Group-B the initial mean and SD was 8.86±1.002, after 3 months of trial treatment it shifted to 4.91±1.074, the improvement was statistically highly significant (p=0.000). But on the basis of mean reduction the patients of group-B showed better improvement in clinical score as compared to Group-A, because of its potent and target oriented approach.[Table 3]

- The present study shows highly significant reduction in mean Uric Acid in both the Groups with certain quantitative differences and found that patients group B (4.63) have showed greater reduction in mean Uric Acid than Ayurveda treated group A (2.67) after trial intervention.
- It was noted that significant reduction in CRP was observed in both the Groups with certain quantitative differences. However, the improvement in terms mean reduction

was greater (3.27) in patients treated with conventional medicine i.e.group B than *Ayurvedic* trial treated group A (mean reduction 3.07).

- It was noted that significant reduction in ESR were observed in both the Groups with certain quantitative differences. However, the improvement in terms of mean reduction was greater (8.37) in patients treated with conventional medicine i.e.group B than *Ayurvedic* trial treated group A (mean reduction 5.32).
- The present study shows a significant improvement in VAS scale in both the group However, the improvement in terms mean reduction was greater (6.03) in patients treated with conventional medicine i.e.group B than *Ayurvedic* trial treated group A (mean reduction 5.97).
- The present study shows a significant improvement inmean reduction of*Ama* grade score in both the groups. However, the mean reduction of *Ama* grade score was greater in patients treated with*Ayurvedic* trial drug as compared Groups B treated with conventional drug.
- The present study shows a significant improvement in Physical and Physiological Domain of WHO Quality of life, but no any significant changes were observed in Social and Environmental Domain of WHO QOL after trial treatment in both groups. But Modern treated group showed slightly better effect as compare to Ayurveda treated group.

Table 4: Effect of treatment on clinical symptoms in 91 cases of Gout

Variable	Group	Mean value			Paired t-test			
		BT	AT	Difference	SDM (±)	t	p	Remarks
ACR EULAR CRITERIA 2015	Group A	8.68	6.85	1.83	1.20	10.422	0.000	HS
	Group B	8.86	4.91	3.95	1.14	23.005	0.000	HS
Uric Acid	Group A	8.34	5.67	2.67	1.133	16.177	0.00	HS
	Group B	8.55	3.92	4.63	0.562	54.63	0.00	HS
CRP	Group A	7.29	3.96	3.327	2.26	10.074	0.000	HS

	Group B	6.84	3.77	3.076	1.534	13.255	0.000	HS
ESR	**Group A**	15.23	10.432	5.327	2.26	4.067	0.000	HS
	Group B	16.21	8.134	8.07	1.534	4.888	0.000	HS
WHO-QOL BREF Domain1(Physical)	**Group A**	54.09	62.13	8.043	9.851	5.597	0.000	HS
	Group B	50.98	62.05	11.068	8.036	9.136	0.000	HS
WHO-QOL BREF Domain2 (Physiological)	**Group A**	48.30	54.38	6.085	7.214	5.597	0.000	HS
	Group B	50.48	61.84	11.36	8.036	10.209	0.000	HS
WHO-QOL BREF Domain3(Social)	**Group A**	64.17	64.30	0.128	0.875	1.000	0.323	NS
	Group B	62.16	62.16	0	0	0	0	NS
WHO-QOL BREF Domain4(Environmental)	**Group A**	61.74	61.77	0.021	0.442	0.330	0.743	NS
	Group B	60.64	60.66	0.023	0.151	1.000	0.323	NS

Probable Mode of Action of *Bodhivriksha ghana vati*: -

This drugs in combination act as antagonists to the main morbid factors i.e., *Dosha* and *Dushya* to cause *Samprapti* v*ighatana* andnotify to all of the clinical symptoms of gout. According to the fundamentals of *Ayurveda*, for the cure of any disease, breaking pathogenesis is the basic line of treatment.

Gout has *vata-rakta* clinical manifestations. Keeping in mind thepathogenesis of Gout, we have selected *Bodhivriksha,* which has *Kashaya*, *Madhura rasa & Guru*, *Ruksha guna, Katu vipaka, Sheeta virya* and *Kapha-pitta shamaka* properties. *Bodhivriksha* is a drug that exhibits *Vichitra pratyarabdhata* properties, including *Madhura* and *Kashayarasa*, *GuruRukshaguna*, *Sheetavirya*, and *Katuvipaka*. The *Madhurarasa* is effective in reducing *vata* and *pittadoshas*, while the *Kashayarasa* possesses properties such as *raktaprasadana*, *amaharatva*, and *mutrasangrahaniya* in its *rukshabhava*. In the present study, an increase in uric acid crystals was

observed in the urine, leading to a decrease in serum uric acid levels. The *mutrasangrahaniya* property of *Bodhivriksha* may cause this effect by detaching uric acid crystals from tissues and eliminating them through urine, which Ayurveda considers one of the malas. Additionally, the *Sheetavirya* of the drug helps reduce pitta, thereby alleviating vitiated *Rakta*. The *Sheetavirya* also promotes an increase in urine output, aiding in the expulsion of uric acid crystals from the body through urine.[xii]

Discussion on Results

Subjective parameters

1. ***Sandhi shoola*** *Bodhivriksha* contains terpenoids, flavonoids, tannins, glycosides, and phenols. Its analgesic properties are attributed to these chemical constituents, which work by inhibiting cyclooxygenase enzymes. This inhibition reduces the synthesis of prostaglandins, thereby significantly alleviating pain.[xiii]

2. ***Sandhi shotha*** **and 3.** ***Sandhistambha-***: The *ruksha guna* and *Kapha pitta shamaka* karma of *Bodhivriksha* are responsible for reducing the swelling and stiffness in patients of gout.

4. ***Daha*** **and 5. Sparshasahyaha-**: The sheeta virya of the drug plays an important role in reducing the pitta thereby reduces vitiated rakta causing reduction in *Daha*.

6. ***TwakVaivarnya-****Madhurarasa* is responsible for the decrease in *Vata* and *pittadoshas* and *Kashayarasa* is having the properties of *raktaprasadana*, and *amaharatva*, which reduces the inflammatory process and flareup of gout.

7. ***Visphota-*** This symptom is clinical not visualised in both the trial group because it is a rarely observed feature in gout. Due to lesser number of patients in both the trial groups, therefore both the group had showed statistically insignificant result.

8. ***Sandhi Vikriti-***This symptom is a rarely seen in the present context of clinical trial because of lesser duration of illness and lesser number of patients in both the group.

Discussion on *Ama* grading Score

Bodhivriksha kashaya *ghanavati*have *kaphashamaka* and *Amaharatva* property which enhance the metabolic activity in the body by metabolising the accumulated *Ama* in the system. *Ama* of Ayurveda is comparable to reactive species, which enhances the inflammatory, pro-inflammatory cascade, which is pacified by *Bodhivrikshaghanavati*. Besides, it also makes easy availability of nutrients to the respective tissues and harmonise the affected body part.

Variable	Group	Mean value			Paired t-test			
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	Group B	8.86	4.91	3.95	1.14	23.005	0.000	HS
Uric Acid	Group A	8.34	5.67	2.67	1.133	16.177	0.000	HS
	Group B	8.55	3.92	4.63	0.562	54.663	0.000	HS
CRP	Group A	7.29	3.96	3.327	2.26	10.074	0.000	HS
	Group B	6.84	3.77	3.076	1.534	13.255	0.000	HS
ESR	Group A	15.23	10.432	5.327	2.26	4.067	0.000	HS
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	Group B	50.48	61.84	11.36	8.036	10.209	0.000	HS
WHO-QOL BREF Domain3(Social)	Group A	64.17	64.30	0.128	0.875	1.000	0.323	NS
	Group B	62.16	62.16	0	0	0	0	NS
WHO-QOL BREF Domain4(Environmental)	Group A	61.74	61.77	0.021	0.442	0.330	0.743	NS
	Group B	60.64	60.66	0.023	0.151	1.000	0.323	NS

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