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A Randomized Comparative Clinical Study to evaluate the effect of *Bodhi Vruksha Twak Kashaya* with *Madhu* and *Guduchi Kashaya* in the Management of *Vatarakta* with special reference to Gouty Arthritis

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ABSTRACT

Background: *Vatarakta* is a disease which is said to affect the population indulging in sedentary lifestyle. In today's era the evolution of technology has reached a point where pretty much anything is available at the touch of a button. The lifestyle of today's population is breeding ground for diseases like *Vatarakta*. Based on the causes, signs and symptoms, *Vatarakta* may be correlated to gouty arthritis in contemporary medicine. Gout affects about 2.1 million worldwide. Its prevalence is increasing; moreover it is a potential signal for unrecognized co-morbidities like obesity, diabetes mellitus, hypertension and renal diseases. In India the prevalence of gout is 2-6 per 1000. The purpose of this study is to explore and find out an effective, less expensive, easily available and well accepted drug with minimal or no complications for this dreadful condition. **Materials and Methods:** 40 patients diagnosed with *Vatarakta* w.s.r Gouty Arthritis were assigned randomly into 2 groups. Group A, were administered *Bodhi Vruksha Twak Kashaya* 50ml B.I.D with *Madhu* and Group B were administered *Guduchi Kashaya* 50ml B.I.D for a duration of 30 days. Assessment was done on day 0, day 15, day 30, and day 45. **Observations and Results:** In the present study Group A showed statistical significant results in all the parameters except for *Sandhishotha* and group B showed statistical significant result in *Sandhishoola*, *Sandhidaha*, *Sparshasahaishnuta* and uric acid levels. **Conclusion:** Overall result shows patients treated with *Guduchi Kashaya* showed better results than patients treated with *Bodhi Vruksha Twak Kashaya* with *Madhu* in *Vatarakta* with special reference to Gouty Arthritis.

Key words: *Bodhivrukshatwak*, *Gouty Arthritis*, *Guduchi Kashaya*, *Vatarakta*.

INTRODUCTION

Ayurveda the science of life, not only deals with curative aspects of the disease but also the preventive measures with which one can prevent the

manifestation of the disease. Today, Unhealthy diet, smoking, alcohol consumption, drug abuse, stress and so on, are the presentations of unhealthy life style which are dominantly noticed in the society. Besides this, emerging new technologies within Information Technology such as the internet, virtual communication networks etc in large have made humans prone to reduced physical activity. These issues have made today's population extremely intern prone for many non-communicable diseases, one such disease is *Vatarakta*.

Vatarakta disease is characterized by the *Dusthi* of *Raktadhatu* and *Vata Dosha*. Vitiating mutually they causing extreme pain and inflammation in the joints, generally in the "*Kara Pada Moolam*" (Metatarso Metacarpo phyleangeal joints) which later spreads to other joints.^[1] The etiopathogenesis starts with

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specific causative factors being both *Vata* and *Rakta* vitiating in nature. The *Sukshmatwa* and *Chalatwa Gunas* of *Vata*, circulates through the *Sandhi* and all the *Srotas*. Similarly, *Rakta* because of its *Drava* and *Sara Guna*, circulates all over. Together they circulate while moving through places where *Siras* are *Vakra*, they face obstruction. These vitiated *Vata Dosha* and *Rakta Dhātu*, amalgamate with the *Pittadi Doshas* locally causing severe pain. The vitiated *Vata* and *Rakta* spreads to the joints similar to that of the *Mushika Visha* also producing *Kandu* (itching), *Toda* (pricking pain), *Daha* (burning sensation), *Vaivarnya* (discoloration), *Sparshasahaishnuta* (tenderness), *Svayatu* (swelling), *Stabdhdta* (stiffness) and *Katina Pidakas* (hard swellings). *Vatarakta* has synonyms *Vata Balasa*, *Khuda Roga* and *Adhyavata*.^[1] This disease is correlated to Gouty arthritis in contemporary science due to its similarity in causative factors, symptomology and pathogenesis. Gouty Arthritis affects about 2.1 million worldwide. Its prevalence is increasing; moreover it is a potential signal for unrecognized co morbidities like obesity, diabetes mellitus, hypertension, renal diseases. In India the prevalence of gout is 2-6 per 1000.^[2]

Gouty arthritis is a picturesque presentation of uric acid disturbance and is the most common crystal arthropathies.^[3] It is a metabolic disease that results from the depositing of mono-sodium urate crystals in the tissues. Increased serum uric acid above 6.8mg/dl is a requirement for the formation of uric acid crystals. These crystals, deposit in all tissues mainly in and around the joints forming tophi.^[4] The current treatment in modern medicine consists of non-steroidal anti-inflammatory drugs which are dangerous in renal insufficiency and gastrointestinal disease and intra-articular injections which are poorly tolerated.^[5] Colchicine or allopurinol or febuxostat are the drugs of choice in hyperuricemia, however they have side effects such as renal toxicity epidermal necrosis, vasculitis and granulomatous hepatitis.^[6] The purpose of this study is to explore an effective, less expensive, easily available and well accepted drug with minimal or no complications for this condition.

In vivo studies on *Bodhi Vruksha Twak Kashaya* have shown promising results in hyperuricemia. *Bodhi Vruksha Twak (Ficus religiosa)* is having *Pittahara* action and *Guru Guna* with a very good analgesic affect.^[7] So, *Bodhi Vruksha Twak Kashaya* has been taken to evaluate its therapeutic efficacy in *Vatarakta* (Gouty arthritis), in comparison to *Guduchi Kashaya* which is mentioned as *Agrya* for *Vatarakta*.^[8]

AIMS AND OBJECTIVES

1. To evaluate the efficacy of *Bodhi Vruksha Twak Kashaya* with *Madhu* in *Vatarakta* with special reference to Gouty Arthritis.
2. To evaluate the efficacy of *Guduchi Kashaya* in *Vatarakta* with special reference to Gouty Arthritis.
3. To compare the efficacy of *Bodhi Vruksha Twak Kashaya* with *Madhu* and *Guduchi Kashaya* in *Vatarakta* with special reference to Gouty Arthritis.

MATERIALS AND METHODS

For the present study patients suffering from *Vatarakta* were selected from OPD, IPD and special camps conducted at the hospital.

The study was approved by the institutional ethical committee (Protocol No:SSIEC/55/2018) and signed informed consent was obtained from all the patients.

Sampling Method and Research Design

Total 40 patients diagnosed with *Vatarakta* were incidentally selected and were randomly assigned into two groups of 20 each as Group A and B respectively.

Diagnostic Criteria: Based on classical sign and symptoms of *Vatarakta* with elevated Serum uric acid levels more than 6.8 mg\dl.

Lab Investigations: Serum Uric Acid.

Inclusion Criteria

- Age group: 18-70.
- Serum uric acid levels more than 6.8 mg\dl.

- Both fresh cases and patients under treatment were taken for the study; the patients under treatment underwent a wash out period of 7 days before starting the study.
- Patients having *Daha* (burning sensation), *Ruja* (pain), *Sandhishotha* (swelling), *Sparshaasahashnuta* (tenderness), in different joints of the body.

Exclusion Criteria

- Secondary hyperuricemia due to leukaemia, lymphoma, polycythaemia.
- Tophaceous gouty arthritis.
- Osteoarthritis
- Subjects with uncontrolled metabolic disorders
- Autoimmune diseases.
- Subjects with renal impairment.
- Any condition interfering the course of treatment were excluded

Intervention

- Group A** - *Bodhi Vruksha Twak Kashaya* 50ml B.I.D and 3 grams *Madhu* before food with warm water.
- Group B** - *Guduchi Kashaya* 50 ml B.I.D before food with warm water.

Assesment Criteria

Subjective Criteria

- Daha* (Burning sensation)
- Sandhishoola* (Pain)
- Sparshasahishnuta* (Tenderness)
- Sandhishotha* (swelling)
- Involvement of the number of joints

Grading was done in the according to the following tables.

Table 1: Grading of Sandhi Shoola.

Grade	Symptoms
0	No pain

1	Pain complained but tolerable
2	Pain complained, taking analgesic
3	Pain complained taking analgesic more than once a day

Table 2: Grading of Sandhidaha.

Grade	Symptoms
0	Absent
1	Transient, no approach for its aversion
2	Frequent, self approach for its aversion
3	Regular, seeking medical advice

Table 3: Grading of Sparshaasahaishnuta.

Grade	Symptoms
0	Absent
1	Deep touch causes pain
2	Mild touch causes pain
3	Severe

Table 4: Grading of Involvement of Joints.

Grade	Symptoms
0	Absent
1	At one joint
2	At two joints
3	At three or more joints

Table 5: Grading of the number of joints Involved.

Grade	Symptoms
0	No Swelling
1	Swelling complained but not Apparent

2	Swelling obvious on 2 joints
3	Obvious swelling on >2 joints

Objective Criteria

Serum uric acid levels

Assessment was done on Day 0, Day 15, Day 30, and Day 45. Data collected was analyzed by using- Paired 't' test, Unpaired 't' test for parametric Mann-U-Whitney, Wilcoxon signed-rank test for non parametric data respectively.

OBSERVATIONS

The incidence is said to be highest in the 3rd-4th decade of life. The same has been observed in the present clinical study. (Table 6).

The incidence of *Vatarakta* is said to be higher in males than females. Women are protected against gout in the pre-menopausal period due to uricosuric effect of female sex hormones. The same has been observed in the present clinical study. (Table 7)

People who indulge in sedentary lifestyle are said to be prone to *Vatarakta*. In the present study, highest incidence is seen in IT Professionals (Table 8). The nature of work of IT professionals is mostly sitting, with very little physical activity and consumption of junk food, with added stress factor which induce metabolic derangement in the body leading to gout.

Gouty arthritis is said as rich man's disease thus, explaining its prevalence in the upper class; however, the middle class people are more prone to stress and strain, which might be the reason for high incidence of *Vatarakta*. The present study shows high incidence in the middle class. (Table 9)

Over weight and obesity are said to be the predisposing factors for gouty arthritis. Same has been observed in the present study. (Table 10)

Gout is said to have a higher incidence in the Muslim population, their diet consists of more non vegetarian food. non vegetarian food increases Serum uric acid levels due to its high protein content. However, Majority of the patients in this study were Hindus

(Table 11), which may be due to predominance of Hindu community in this particular region.

Gout is a purine metabolism disorder, high intake of purines (protein rich food) is one of the patented causes for gout, the same has been observed in the study. (Table 12)

Alcohol consumption is considered a potential risk for gout. However, in this study (Table 13), the incidence of gout was high in patients with no alcohol consumption and smoking. As the study was conducted at a traditional holistic center where alcohol or smoking was not encouraged.

The incidence of distribution according to the symptomatology is shown in (Table 14)

Table 6: Showing the incidence of disease with relation to age.

Age	Group A	Group B	Total
20-30	1	1	2 (5%)
30-40	6	9	15 (37.5%)
40-50	4	4	8 (20%)
50-60	3	3	6 (15%)
60-70	6	3	9 (22.5%)

Table 7: Showing the incidence of disease with relation to Gender.

Gender	Group A	Group B	Total
Male	15	17	32(80%)
Female	5	3	8(20%)

Table 8: Showing the incidence of disease with relation to Occupation.

Occupation	GroupA	GroupB	Total
Housewife	3	1	4 (10%)
Farmer	2	1	3 (7.5%)

Business	2	5	7 (17.5%)
IT Eng	4	5	9 (22.5%)
Civil Eng	0	2	2 (5%)
Retired	7	2	9 (22.5%)
Others	2	4	6 (15%)

Table 9: Showing the incidence of disease with relation to Socio-economic Status.

Socio eco status	Group A	Group B	Total
Lower-middle class	0		0 (0%)
Upper-middle class	12	7	19 (47.5%)
Upper class	8	13	21 (52.5%)

Table 10: Showing the incidence of disease with relation to Body Mass Index.

BMI	Group A	Group B	Total
Normal	7	8	15 (37.5%)
Over weight	11	6	17 (42.5%)
Obese	3	6	9 (22.5%)

Table 11: Showing the incidence of disease with relation to Religion.

Religion	Group A	Group B	Total
Hindu	18	20	38 (95%)
Muslim	1	0	1 (2.5%)
Christian	1	0	1 (2.5%)

Table 12: Showing the incidence of disease with relation to the Food Habits.

Food habits	Group A	Group B	Total
Veg	4	4	8 (20%)

Mixed	16	16	32 (80%)
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Table 13: Showing the incidence of the disease with relation to the Habits.

Habits	Group A	Group B	Total
Nil	13	10	23 (57.5%)
Smoking	0	0	(0%)
Alcohol	2	2	4 (10%)
both	5	8	13 (32%)

Table 14: Incidence of observation of symptomatology.

Symptoms	Group A	Group B	Total
Sandhi Shoola	20	20	40 (100%)
Sandhi Daha	0	0	(0%)
Sparshaasahaishnuta	2	2	4 (10%)
Sandhishotha	5	8	13 (32%)

RESULTS

In the present study patients treated with *Bodhi Vruksha Twak Kashaya* with *Madhu* showed high statistically significance result in *Sandhishoola*, *Sandhidaha* and serum uric acid level with p value <0.001 and statistical significance in *Sparshasahaishnuta*, Number of joints involved with p value <0.05. while patients treated with *Guduchi Kashaya* showed highly statistically significant results in *Sandhishoola*, *Sparsha Asahaishnuta* and uric acid with p value <0.001 and significant results in, *Sandhidaha*, *Sparsha Asahaishnuta* with p value <0.05. Overall result shows *Guduchi Kashaya* better than *Bodhi Vruksha Twak Kashaya* with *Madhu* in *Vatarakta* w.s.r Gouty Arthritis. Between the groups there is no statistically significance seen in any of the parameters.(Table 10 &11)

Table 15: Effect of medicine on chief complaints in the patients of Vatarakta in Group A.

Symptoms	Mean Score		P value
	B.T	A.T	
Sandhishoola	3.00	1.40	0.001
Sandhidaha	1.15	0.40	0.004
Sparshaasahaishnuta	0.55	0.05	0.026
Number of joints	2.25	1.70	0.053
Sandhishotha	0.70	0.65	0.339
Serum Uric Acid	8.2485	7.7950	0.000

Table 16: Effect of medicine on chief complaints in the patients of Vatarakta in Group B.

Symptoms	Mean Score		P value
	B.T	A.T	
Sandhishoola	3.00	2.35	0.006
Sandhidaha	1.35	0.95	0.011
Sparshaasahaishnuta	0.80	0.05	0.001
Number of joints	2.25	1.85	0.109
Sandhishotha	0.20	0.10	0.157
Serum Uric Acid	7.9400	7.1650	0.000

Overall, applying Chi Square Test, Group A shows better result the Group B (Table No 17).

Table 17: Showing the Over All Improvement

Parameters	Groups	UN	ML	MD	MR
Sandhishoola	A	4	4	4	8
	B	11	5	1	3
Sandhidaha	A	11	2	0	7

	B	13	5	1	3
Sparsha Asahaishnuta	A	14	0	0	7
	B	7	0	0	13
Number of joints involved	A	15	0	0	5
	B	17	0	0	3
Sandhishotha	A	15	1	0	4
	B	18	0	0	2
Serum Uric acid levels	A	1	1	7	11
	B	1	1	-	18

UN - Unchanged, ML - mild, MD - moderate, MR - Marked Relief, A - Group A, B - Group B.

DISCUSSION

In the present study, it was observed that both *Bodhi Vruksha Twak Kashaya with Madhu* and *Guduchi Kashaya* effectively reduced the signs and symptoms of *Vatarakta*, but with regard to Serum Uric Acid, *Guduchi Kashaya* showed better results. *Guduchi* contains alkaloids such as berberine which is said to be a xanthine oxidase inhibitor.^[8] Additionally, the plant also contains different alkaloids such as, diterpenoid lactones, glycosides and polysaccharides which are noted to have uricosuric activity,^[9] because of which there is additional excretion of uric acid. Thus, showing good effect in reducing the serum uric acid levels in the blood.

Additionally, *Guduchi* being *Tridosahara* with *Tikta Rasa*, possessing anti-inflammatory and analgesic properties^[8] helps in the management of the disease *Vatarakta*.

Sandhishoola

The effect of both the drugs was highly significant with slightly better result in group A. The same was observed on the 15th day. By the end of the treatment all the patients in Group A showed improvement in *Shoola*, while in group B, 10 patients had no

improvement in *Shoola*. The analgesic effect of *Bodhi Vruksha* is due to its chemical constituents which are mediated via inhibition of cyclo oxygenases leading to the inhibition of prostaglandin synthesis,^[10] reducing the pain significantly (Table 13 and 14).

Sandhidaha

The effect of both the drugs was significant with slightly better result in Group A. The anti inflammatory effect of *Bodhi Vruksha* is caused due to its chemical constituents in which is mediated via inhibition of cyclo oxygenases leading to the inhibition of prostaglandin synthesis,^[10] reducing the burning sensation.

Sparsha Asahaishnuta

Both *Bodhi Vruksha* and *Guduchi* showed statistically non significant results in treating the symptom *Sparsha Asahaishnuta*, the above results were probably due to, both the drugs posses alkaloids, glycosides, steroids.^{[7],[8]}

Number of Joints

In reducing the symptoms in the number of joints involved both the groups showed improvement but, Group A showed better results than group B. Both *Bodhi Vruksha* and *Guduchi* contain alkaloids which posses anti inflammatory effect.^{[7],[8]}

Sandhi Shotha

In treating the symptom *Sandhishotha*, *Guduchi Kashaya* showed better results than *Bodhi Vruksha Kashaya*. *Guduchi* possesses *Tridoshahara*, and has *Shophahara* and *Mutrala*^[10] property which must have acted in reducing *Sandhi Shotha*. *Tinospora cordifolia* contains, alkaloids, which inhibit the action of prostaglandins showing its anti inflammatory effect,^[8] its anti inflammatory helps in reducing edema.

Discussion on Uric Acid

Group B shows better result than Group A with no statistical significance with P value >0.05 in reducing the serum uric acid levels. *Guduchi* contains alkaloids such as berberine which is said to be a xanthine oxidase inhibitor.^[8] Additionally, the plant also contains different alkaloids such as, diterpenoid

lactones, glycosides and polysaccharides which are noted to have uricosuric activity,^[9] because of which there is additional excretion of uric acid. Thus, showing good effect in reducing the serum uric acid levels in the blood.

Table 18: Showing the results of intervention on Symptoms in Group A

Group A	B.T				15 th day				A.T			
	G R 0	G R 1	G R 2	G R 3	G R 0	G R 1	G R 2	G R 3	G R 0	G R 1	G R 2	G R 3
C.F	0	1	2	3	0	1	2	3	0	1	2	3
<i>Sandhish oola</i>	0	2	1 2	7	2	3	9	7	4	3	9	2
<i>Sandhida ha</i>	5	6	1 1	0	1 1	4	5	0	9	5	6	0
<i>Sparshaa sahaishn uta</i>	7	1 2	2	0	1 4	6	0	0	1 9	1	0	0
Number of joints involved	0	6	1 0	4	2	5	9	4	3	5	9	3
<i>Sandhish otha</i>	1 6	4	0	0	1 7	3	0	0	1 8	2	0	0

Table 19: Showing the results of intervention on Symptoms in Group B

Group B	B.T				15 th day				A.T			
	G R 0	G R 1	G R 2	G R 3	G R 0	G R 1	G R 2	G R 3	G R 0	G R 1	G R 2	G R 3
C.F	0	1	2	3	0	1	2	3	0	1	2	3
<i>Sandhish oola</i>	0	1	1 2	7	5	4	8	3	7	4	8	1
<i>Sandhida ha</i>	6	5	9	0	1 1	6	3	0	1 4	5	1	0
<i>Sparshaa sahaishn uta</i>	1 3	4	3	0	1 8	2	0	0	1 9	1	0	0
Number of joints	1	8	4	6	6	4	4	6	6	5	4	5

involved												
Sandhish otha	1 0	6	4	0	1 2	4	4	0	1 5	3	2	0

CONCLUSION

Vatarakta disease is characterized by the *Dusthi* of *Vata Dosha and Rakta Dhatu* vitiating each other causing extreme pain and inflammation in the joints. This disease is correlated to gouty arthritis in contemporary science. The current treatment in modern medicine either is poorly tolerated or they have complications such as renal toxicity, epidermal necrosis, vasculitis and granulomatous hepatitis. Hence, in the present study, *Bodhi vruksha Twak Kashaya* with *Madhu* and *Guduchi Kashaya* was given in Group A and Group B respectively. Both *Bodhi Vruksha Twak Kashaya* with *Madhu* and *Guduchi Kashaya* show effect in the symptoms of *Vatarakta*. *Guduchi Kashaya* showed better results in reducing the serum uric acid levels in the blood compared to that of *Bodhi vruksha Twak Kashaya* with *Madhu*. Although both the groups showed significant results, patients of group A expressed greater relief in pain and burning sensation compared to that group B. Further the study can be conducted in a larger sample and longer duration of drug administration with analysis of urate crystals from the inflamed joints.

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