WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 7, Issue 19, 705-716. Research Article ISSN 2277– 7105

EFFECT OF *VATARAKTAHARA* CAPSULES IN *VATARAKTA* WITH SPECIAL REFERENCE TO HYPERURICEMIA

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Article Received on
12 October 2018,

Revised on 01 Nov. 2018,
Accepted on 22 Nov. 2018

DOI: 10.20959/wjpr201819-13478

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ABSTRACT

Hyperuricemia/gout is a commonest form of inflammatory arthritis affecting elderly but it appears to be poorly managed due to absence of sufficient treatment strategies and guidelines. Incidence and prevalence of gout has been increased due to either faulty life styles or due to the adverse effect of certain drugs. Both Diagnosis and treatment poses a challenge due to its remittent nature. In *Ayurveda*, several medicinal plants have been described and used in the management of gout (*Vatarakta)* due to their anti-inflammatory and analgesic activity. The present study was done to assess the effect of trial formulation *Vataraktahara* Capsules on the patients of *Vatarakta*. Drug was given to thirty patients for 2 months after the written informed consent. The effect of trial formulation was obtained after statistical analysis of the data obtained. Study showed highly significant results in criteria *Sandhi Shoola*, *Sandhi Shotha*, *Sparsha Asahyata*, *Raga*, *Vidaha* and *Stabdhata* with $p<0.001$. In *Shithilta*, significant improvement was recorded ($p<0.01$). In *Tvak Vaivarnyata*, 100% relief was noted. Insignificant improvement ($p>0.05$) was seen in *Hritspanda*. No effect was found in *Sandhi Vikriti*. 18.92% reduction of serum uric acid was recorded after the trial with highly significant result. So can be concluded that the trial formulation, *Vataraktahara* Capsules contains *Guggulu*,

Guduchi, *Trifla* etc. which is a good combination of *Vedanasthapana*, *Rasayana*, *Shothaghna*, *Mutral*, *Deepan* and *Amapachak Dravyas*, hence quite effective in gout to lower the symptoms and frequency of gout flares without any side effects.

KEYWORDS: Hyperuricaemia, Gout, *Sandhi*, *Vatarakta*, *Vedanasathapan*.

1. INTRODUCTION

Hyperuricemia is a condition in which there is abnormality in purine metabolism and can result either due to the overproduction or under excretion of uric acid or both, predisposing the individual to gout. Gout manifests due to the deposition of monosodium urate monohydrate crystals in joints and tissues. These crystals after deposition lead to inflammatory arthritis, tophi formation, renal disease and urolithiasis which can later impair the quality of life. With a history spanning more than 2500 years, gout is among the oldest recognized disease. In recent decades, the rate of gout has markedly increased which is possibly due to dietary and life style changes. Number of self reported cases of gout in U.S.A. increased from 2.1 million to 3.0 million over a period of ten years (1990-1999) making it more prevalent than Rheumatoid Arthritis.[1] Till date, there is no permanently cure of the disease due to its relapsing and remittent nature. Various studies have identified gout as a risk factor for NIDDM[2], Metabolic syndrome[3] and CAD.[4] In present era, the main challenge in a patient of gout is not only its relapsing and remittent nature but more importantly, to manage its associated co morbidities. Gout resembles the description of *Vatarakta* described in *Ayurvedic* literature. Various medicinal plants and polyherbal formulations have been mentioned in *Ayurvedic* literature for the management of *Vatarakta*/gout. Few of them are *Guduchi (*T.cardiofolia*), Trifla, Guggulu* (C.mukul*)* etc. Many researches have also been done to assess their anti-inflammatory, analgesic and antiarthritic activity which showed very significant effect.[5-9] The present research is based on clinical trial of a polyherbal formulation which is a combination of known *Vatraktahara* herbal drugs.

2. MATERIALS AND METHODS

Ethics

The trial was approved by Institutional Ethical Committee. Written informed consent from the subjects was taken before initiating the trial.

Research Design

Sample

The present study was designed to be open trial with single group study. Total 30 patients were selected randomly from OPD and IPD of Department of *Kayachikitsa*, RGGPG Ayurvedic Hospital, Paprola from the month January 2011 to September, 2011.

Selection of Subject

Patients having age between 18-70 years, serum uric acid level >7 mg/dl in males and >6 mg/dl in females and not having any associated chronic ailments were registered.

Individuals with age <18 yrs. and >70 yrs., suffering from other arthritic disorder like RA, Diabetes mellitus, Chronic renal disease, Thyroid disorder, Hemolytic anemia, ALD and Myeloproliferative disorders were excluded from the study.

Variables for effect

The following criteria or variables were assessed before and after the drug administration.

1) *Sandhi Shoola* (Joint pain)
2) *Sandhi Shotha* (Swelling)
3) *Sparsha Asahyata* (Tenderness)
4) *Raga* (Redness)
5) *Tvak Vaivarnya* (Discolouration)
6) *Vidaha* (Burning sensation)
7) *Stabdhata* (Stiffness)
8) *Shithilta* (Fatigue)
9) *Hritspandan* (Palpitation)
10) *Sandhi Vikriti* (Joint deformity)
11) Serum uric acid level before and after the trial

Procedure

The study was approved by Institutional Ethical Committee, RGGPGA Hospital, Paprola (H.P.). Prior to the trial, subjects were explained about the drug and trial in the form of patient information sheet. After that, the volunteers were recruited and written informed consent was obtained by them.

Test Drug

The trial formulation, *Vataraktahara* Capsules is a polyherbal preparation, containing following 14 indigenous drugs (each capsule weighing 890 mg).

a) Shudhha Guggulu (399 mg)

b) Extracts (5)- (mass extract-173 mg each of ; *Guduchi* 2) A*malaki* 3*) Haritaki* 4) *Vibhitak* 5) *Gokshuru*

c) Powder (10)- 228 mg (each weighing 22.8 mg)

*1) Dantimoo*l 2) *Vidang* 3) *Amrita* 4) *Trifla Churna* 5) *Dalchini* 6) *Shunthi* 7) *Marich* 8) *Pippalimool* 9) *Trivrit* 10) *Nagarmotha*

d) Inert excipient – 90 mg

The trial drug was prepared and provided by Shree Dhanvantri Herbals, Amritsar to the standards of GMP. A detailed controlled animal study had already been conducted by Department of Pharmaceutical Sciences, GNDU, Amritsar for its analgesic, anti-inflammatory and hypouricemic effects which were found highly satisfactory.

Monitoring of subjects

All the subjects consumed the formulation for prescribed duration i.e. for 60 days with follow up after every 20 days. 2 patients dropped out in between the course. So the effect of therapy was seen only in 28 patients.

Statistical analysis

The data was analyzed in form of Mean score before and after treatment, standard deviation and standard error. Student paired ‘t’ test was carried out for statistical significance. Demographic profile and pattern of joint involvement of 30 patients was also observed.

❖ RESULTS

Demographic Profile of 30 subjects (Table no.1,2)

Male to female ratio was 20:10. 75% of the patients were in the age range from 51-70 years. In occupation wise distribution, contribution of businessmen and inservice class was 60%. 36.67% patients were educated up to metric level, 23.33% were educated up to primary level and similar percentage patients were graduate. 40% subjects were of middle socioeconomic group. Total 43.33% patients were addicted to alcohol. 70% patients were having sedentary lifestyle. 63.3% patients were taking mixed diet. 40% patients had BMI >25. Hypertension

(20%), CAD (3.33%) and renal calculus (10%) were other associated diseases found in patients.

Table No. 1: Demographic Profile of Patients.

Age	No. of Patients (n)	Percentage
18-30 years	1	3.33%
31-40 years	3	10%
41-50 years	5	16.67%
51-60 years	14	46.67%
61-70 years	7	23.33%
Sex		
Males	20	66.67%
Females	10	33.33%
Occupation		
Businessman	9	30%
Inservice class	9	30%
Housewife	7	23.33%
Retd person	3	10%
Student	1	3.33%
Farmer	1	3.33%
Qualification		
Primary	7	23.33%
Metric	11	36.67%
Graduate	7	23.33%
Illiterate	5	16.67%
Socio economic status		
Lower	10	33.33%
Middle	12	40%
Upper	8	26.67%

Table No. 2: Demographic Profile of Patients.

Addiction		
No addiction	15	50%
Alcohol	8	26.67%
Alcohol and smoking	5	16.67%
smoking	2	6.67%
Lifestyle		
Sedentary	21	70%
Active	9	30%
BMI/Weight		
<18.5 (underweight)	1	3.33%
18.5-24.9 (normal)	17	56.67%
>25 (overweight and obese)	12	40%
Other associated diseases		
Hypertension	6	20%
CAD	1	3.33%
Renal calculus	3	10%

Disease characteristic of 30 subjects (Table no. 3)

60% patients had acute onset of disease. Only 16.67% patients had positive family history of gout. Asymmetrical involvement of joints was recorded in 76.67% of patients. In chronicity wise distribution, 60% patients had duration of illness less than 2 years; 2-4 years duration was recorded in 16.66% patients; 6.67% and 10% patients had duration of illness 4-6 years and 6-8 years respectively. 66.67% patients had involvement of Ist metatarsophalangeal joint followed by knee, ankle and interphalangeal joint with 43.33%, 23.33% and 16.67% involvement respectively.

Table No. 3: Disease characteristic of Patients.

Nature of onset	No of patients (n)	Percentage
Acute	18	60%
Insidious	12	40%
Family history		
Present	5	16.67%
Symmetry of involved joints		
Asymmetrical	23	76.67%
Chronicity		
Less than 2 years	18	60%
2-4 yrs.	5	16.67%
4-6 yrs.	2	6.67%
6-8 yrs.	3	10%
8-12 yrs.	2	6.67%
Joints involved		
MTP joint (Ist)	20	66.67%
Knee	13	43.33%
Ankle	7	23.33%
Interphalangeal joint	5	16.67%
Elbow, wrist, instep of foot	3 (each)	10% (each)

Efficacy outcomes in 28 patients (Table no. 4,5)

Grade score system was designed for assessing the improvement on subjective criteria (except serum uric acid level) in *vatarakta* patients. There was highly significant improvement in criteria of *Sandhi shoola* (joint pain), *Sandhi Shotha* (joint swelling), *Sparsha Asahyata* (tenderness), *Raga* (redness), *Vidaha* (burning sensation) and *Stabdhata* (stiffness) with $p<0.001$. 100% relief was recorded in *Tvak Vaivarnya* (discolouration). Significant relief with $p<0.01$ was observed in *Shithilta* (fatigue). In *Hritspandan*, 24.8% relief was there with insignificant result ($p>0.05$). No improvement was recorded in *Sandhi Vikriti* (joint deformity). 18.92% reduction of serum uric acid with highly significant result was recorded after the trial. There was no considerable change in hematological as well as

biochemical values. No drug toxicity or severe side effect was observed during the course of trial.

Table no. 4: Statistical Data showing Efficacy outcome in Patients.

Criteria	N*	Mean Score (BT^x)	Mean score (AT^+)	%age relief	SD±	SE±	t	p
Sandhi shoola	28	2.43	0.75	69.1%	0.55	0.10	16.21	<0.001
Sandhi shotha	15	1.93	0.4	79.3%	0.83	0.22	7.11	<0.001
Sparsha asahyata	23	1.56	0.35	77.6%	0.49	0.10	11.51	<0.001
Raga	12	1.92	0.25	86.98%	0.78	0.23	7.42	<0.001
Vidaha	23	1.96	0.74	62.2%	0.85	0.18	6.87	<0.001
Vaivarnya	02	2.0	0	100%	-	-	-	-
Stabdhata	22	1.45	0.54	62.76%	0.53	0.11	8.11	<0.001
Shithilta	14	1.36	0.64	52.9%	0.73	0.19	3.68	<0.01
Hritspandan	03	1.33	1.0	24.8%	0.58	0.33	1.01	>0.05
Sandhi vikriti	02	1.0	1.0	0%	-	-	-	-

(N*-no. of patients with specific subjective criterion, BT^x- before trial, AT^+- after trial).

Table no. 5: Data showing effect on Serum uric acid level.

N*	Mean Serum uric acid level (BT^x)	Mean Serum uric acid level (AT^+)	%age reduction	SD±	SE±	t	p
28	7.907	6.411	18.92	1.04	0.197	7.604	<0.001

(N*-no.of patients with specific subjective criterion, BT^x- before trial, AT^+- after trial).

Overall effect of therapy (Table no. 6)

The overall effect of therapy i.e. *Vataraktahara* Capsules on Vatarakta (hyperuricemia) suggests that 7.14% patients showed complete abolishment (100% relief) of signs and symptoms of gout; 35.71% patients showed excellent improvement (75-99% relief), 53.57% patients showed moderate improvement (50-74% relief). Only 3.57% patients showed mild improvement (25-49% relief) in their signs and symptoms. No one deteriorated or showed unimprovement with the trial formulation.

Table no. 6: Overall effect of therapy.

Overall assessment	No. of Patients	Percentage
Complete abolishment	02	7.14%
Excellent improvement	10	35.71%
Moderate improvement	15	53.57%
Mild improvement	01	3.57%
No improvement	00	0%

❖ DISCUSSION

Ayurveda has been showering its valuable treasures to mankind since time unknown. *Guggulu* and *Guduchi* preparations are assumed to be one among the finest *Shaman Aushadh* in the same. Literature enlists a number of such *Guggulu* preparations in the management of *Vatarakta* so the present study was aimed to assess the effect of formulation, *Vataraktahara* capsules containing *Guduchi, Guggulu, Trifla* etc. on selective features of *Vatarakta* (hyperuricemia). Effect of therapy was observed on various assessment criteria like *Sandhi Shoola, Sandhi Shotha, Sparsha Asahyata, Raga, Vidaha, Tvak Vaivarnyata, Stabdhata, Shithilta, Hritspandan, Sandhi Vikriti* as well as serum uric acid level.

The drugs combinely act as antagonists to the morbid *Doshas* i.e. *Vata Pradhan Tridosha,* morbid *Dushya i.e. Rakta Dhatu* along with the correction of *Jatharagni* as well as *Dhatvagni mandya*. In *Vatarakta, Doshas* involved are *Shakhagata* and *Madhyam Rogamargagata.* Its *Utkleshan* by means of *Vridhhi, Vishyandan, Paka* and *Srotoshodhan* leads to movement of these *Shakhagata Doshas* towards *Koshtha* and from *Koshtha,* these *Doshas* are thrown out of the body either through *Mutravirechan* or *Purishvirechan.*

Table no. 7: Combined ayurvedic Pharmacological action of the drug.

Deepan	***Pachan***	***Vishyandan and Srotoshodhan***	***Vedana-sthapan***	***Virechana***	
				Mutra virechan	***Purish virechana***
Guduchi, Amalaki, Haritaki, Danti, Mustak, Vidang, Pippali, Tvak	*Guduchi, Haritaki, Mustak, Vidang, Trikatu, Tvak*	*Guggulu, Marich, Shunthi, Vidang, Danti, Trivrit, Tvak*	*Guggulu, Guduchi, Haritaki, Vibhitak, Gokshur, Danti, Shunthi, Tvak*	*Guduchi, Amalaki, Haritaki, Gokshur, Mustak, Vidang, Pippali, Marich, Tvak*	*Trivrit, Danti, Amalaki, Vibhitak, Pippali*

Besides all these, some of these drugs have R*asayana, Shothahara, Vatanuloman* and *Medohara* properties which overall help in relieving the symptoms of *Vatarakta*.

Modern Pharmacological action of the drug (Table no.8)

Various experimental studies on most of these drugs have confirmed their anti- inflammatory, anti arthritic and analgesic activity. Diabetes mellitus, dyslipidemia etc. are found in association with gout. Few drugs like[10] *Guggulu*[11], *Shunthi, Mustak, Vidanga, Haritaki, Amalaki* and *Vibhitak* have hypolipidemic activity. In human studies also, it corrects lipid profile. Some other drugs[12] like *Trifla, Guduchi* have hypoglycemic action.

Table no. 8: Chemical composition of individual drugs.

Triterpenes (Anti inflammatory, Immuno-modulator)	Diterpenes and sesquiterpene (Anti-inflammatory)	Polyphenols (Anti inflammatory, anti-arthritic)	β- sitosterol (Anti inflammatory, hypolipidemic)	Glycosides (Anti inflammatory Antidiabetogenic)	Piperine (Analgesic and antipyretic)
Guggulu[13] *Vibhitak*[14]	*Guggulu*[13], *Danti*[15] *Guduchi*[16], *Mustak*[17], *Pippali*[8], *Marich*[19]	*Amalaki*[20], *Vibhitak*[14], *Haritaki*[21], *shunthi*[22],	*Guggulu*[13], *Vibhitak*[14], *Gokshur*[23], *Mustak*[17], *Trivrit*[24], *Marich*[19]	*Guduchi*[16], *Gokshur*[23], *Danti*[15], *Trivrit*[24], *Vidang*[25], *Pippali*[18], *Tvak*[26]	*Marich*[19] *Pippali*[18]

In the demographic profile and disease characteristics, it was observed that maximum patients were of age group 51-60 years and males constituted approximately two third of the sample. Majority of them were either businessmen or in service class (possibly due to their sedentary lifestyle). Earlier the disease was known as 'Disease of Lords' because it was seen mostly in wealthy people but now with the invention of cheap fast food, no one is safe from gout. This may be the reason that major portion of the trial group was educated up to metric level and was from middle socioeconomic group followed by lower socioeconomic group. Alcohol and non vegetarian diet, both are prime factors for the precipitation of gout attack. According to data, approximately, half of the patients were alcoholic and more than half were on mixed diet. Approximately two third were having sedentary lifestyle. Hypertension and overweight/obesity were found to be commonest associated conditions in the sample. Commonest involved joint was 1st metatarsophalangeal joint followed by knee and ankle with maximum percentage of asymmetrical joints involvement. Majority of the patients had duration of illness less than 2 years.

The analysis clearly indicates that the patients improved considerably as a result of *Ayurvedic* treatment. There was statistically significant improvement in most of the criteria which were selected to evaluate the effectiveness of trial drug.

The present study was limited to the period of 60 days. The future research should focus on longer treatment duration. Further studies are also required to assess the effect of drug on lipid profile as well as blood sugar level after long duration administration.

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