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RESEARCH ARTICLE

An Open Label Efficacy Study of *Amrita Guggulu* and *Pinda Taila* in the Management of Hyperuricemia in Gout (*Vatarakta*) Patients

[1]Harbans Singh, [2]Rajesh Sannd, [3]Laxman W Bhurke, [4]Krishna Kumari, [5]Renu Singh, [6]SK Vedi, [7]Adarsh Kumar [8]Bharti, [9]Rakesh Rana, [10]Richa Singhal, [11]N Srikanth, [12]MM Padhi, [13]Kartar Singh Dhiman

ABSTRACT

Background: *Vatarakta* vis-à-vis gout is a common condition in both primary care and specialist practice. Gout is a systemic disease characterized by manifestations of chronic underlying hyperuricemia, resulting in the deposition of monosodium urate crystals in various tissues. Gout is the most common of the crystal induced arthritis due to disturbed uric acid metabolism and precipitation of urate crystals in extracellular space of joints, periarticular tissue, bones, and other organs.

Aim and objective: To explore the therapeutic efficacy and safety of *Amrita Guggulu* and *Pinda Taila* in the management of hyperuricemia in gout (*Vatarakta*) patients.

Materials and methods: A total of 100 cases (25–65 years) of primary gouty arthritis fulfilling the diagnostic criteria as recommended by the American College of Rheumatology were selected for the present study from outpatient department of the Central Ayurveda Research Institute for Respiratory Disorders Patiala and Regional Ayurveda Research Institute for Urinary Disorders, Jammu, India, irrespective of their sex, religion, and socioeconomic status. Only those patients who presented themselves with at least 6 of 12 criteria of American College of Rheumatology (1977) were selected for the clinical trial. *Amrita Guggulu* was given 1000 mg twice daily orally and *Pinda Taila* was applied locally 10 mL twice daily for 84 days.

Results: The trial therapy was assessed based on the improvement in clinical features, Visual Analog Scale (VAS) score, Patient's Global Assessment Scale score, Physician's Global Assessment Scale Score, SF-36 Health Survey Score for quality of life (QOL), and biochemical parameters. Each patient was subjected to routine blood test, serum uric acid, liver function tests, and renal function tests before treatment, after 28 days of treatment, and after 84 days of treatment. The trial combination showed statistically significant improvement in the clinical manifestations, QOL as well as reduction in marker of hyperuricemia, i.e., serum uric acid; the mean serum uric acid at the baseline was 7.76 mg/dL, which was reduced to 6.50 mg/dL after the trial period of 84 days. There was also decrease in the level of VAS score, Patient's Global Assessment Scale score, and Physician's Global Assessment Scale score. There were no impairment in liver function test and renal function test, indicating the good safety profile of trial therapy.

Conclusion: Hence, *Amrita Guggulu* and *Pinda Taila* drug combination is an effective and safe remedy for gouty arthritis (Vatarakta) patients.

Keywords: *Amrita Guggulu*, Gout, Joint diseases, *Pinda Taila*, Therapeutic efficacy.

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[1,3,5,6]Research Officer, [2,4,7,8]Assistant Director, [9]Statistical Officer [10]Statistical Assistant, [11]Deputy Director General, [12]Former Deputy Director General, [13]Director General

[1]Central Ayurveda Research Institute for Respiratory Disorders Patiala, Punjab, India

[2,5,6,7,9-13]Central Council for Research in Ayurvedic Sciences New Delhi, India

[3,4]Regional Ayurveda Research Institute for Urinary Disorders Jammu, Jammu and Kashmir, India

[8]Central Ayurveda Research Institute for Cardiovascular Diseases, New Delhi, India

Corresponding Author: Renu Singh, Research Officer, Central Council for Research in Ayurvedic Sciences, New Delhi, India Phone: +9188826570500, e-mail: drrenusingh@yahoo.com

INTRODUCTION

Joint diseases are becoming the main health problem in the present era as a result of changes in diet, lifestyle, and environmental factors. *Vatarakta* vis-à-vis gout is a common condition in both primary care and specialist practice.[1] Although not life-threatening, it has a significant impact on quality of life (QOL). *Vatarakta* vis-à-vis gout is a very painful condition, and it curtails the output or day-to-day work of the patient. It is the commonest crystal induced arthropathy occurring in men over 40 years of age, presenting usually in the form of "*podagra*" (acute onset of pain, erythema, and swelling of the first metatarsophalangeal joint).[2] It has been called as "*the disease of kings*" due to its association with rich foods and alcohol consumption.[3,4] Gout is a crystal-deposition disease that results from chronic elevation of uric acid levels above the saturation point for monosodium urate monohydrate (MSUM) crystal formation and it is associated with intense pain and enhanced vascular permeability evidenced by edema and erythema that may extend beyond the joint

margin.[5,6] The fundamental biochemical hallmark of gout is hyperuricemia and can result from increased production or decreased excretion of uric acid or from a combination of the two processes. Uric acid is the end product of metabolism of purines. Elaborate descriptions of *Vatarakta* (gout) in traditional Indian medicine show that it was one of the main articular diseases in the past.[7-9] Descriptions of several disorders having symptom of pain, inflammation, and burning sensation in the joints have been referred to in Vedic literature. Sedentary lifestyle is one of the main etiological factors of *Vatarakta*. Many people, due to their nonmanual work practices, are having sedentary lifestyle. When aggravated *Vata* is obstructed by aggravated *Rakta*, thus obstructed *Vata* again vitiates the *Rakta*. This pathological state is known as *Vatarakta* or *Vatasonitam*.[7] The chief complaint of the patient is severe *Sandhi-shula* (joint pain) onset on *Hasta* (hand), *Pada mulagata sandhi* (MTP joints), and then migrates to other *Sandhi* (joint) in a way similar to *Akhuvisa* (rat poison).[8] It produces various signs and symptoms like *Ruk* (excruciating pain), *Swayathu* (swelling), *Daha* (burning sensation), *Stabdha* (stiffness of joint), *Shyava-rakta Varna* (blackish red in color), *Sparsha-asahetwa* (hyperesthesia),[9] etc. Ayurvedic scholars have correlated *Vatarakta* with gout based on its various etiological factors and clinical manifestations. The mainstay of treatment during the acute attack is the administration of anti-inflammatory drugs, such as colchicines, nonsteroidal anti-inflammatory drugs (NSAIDs), or glucocorticoids depending on the age of the patient and comorbid conditions. The colchicines and NSAIDs may be quite toxic in the elderly, particularly in the presence of renal insufficiency and gastrointestinal disorders.[10] Therefore, there is a definite need to explore more efficacious and radical cure to this illness. Ayurveda in its herbarium has lots of ayurvedic formulations which can fill up this gap. Based on the textual and clinical experience, compound drugs *Amrita Guggulu* and *Pinda Taila* were selected as hypouricemic agent for the clinical trial in patients of *gout (Vatarakta).* This study was planned to find out the efficacy and safety of *Amrita Guggulu* and *Pinda Taila* in hyperuricemia in gout patients. After examining the pharmacological properties and pharmacological actions of constituents of selected *Amrita Guggulu* and *Pinda Taila*, it appeared that this combination might be effective in the management of gout *(Vatarakta).* Therefore, in order to develop evidence-based data on the efficacy and safety of *Amrita Guggulu* and *Pinda Taila* in the management of gout (*Vatarakta*) on scientific parameters, the present clinical trial was conducted.

OBJECTIVES

To study the therapeutic efficacy and safety of two classical Ayurvedic formulations, *Amrita Guggulu* and *Pinda Taila*, in the management of hyperuricemia in gout (*Vatarakta*) patients.

MATERIALS AND METHODS

Study Design

The study was a prospective open label multicenter trial executed at two peripheral centers of Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, New Delhi, India. The study protocol was approved by the respective Institutional Ethical Committee of the Institutes. The study was conducted in accordance with World Health Organization Good Clinical Practice Guidelines. Written informed consent was taken from all the participants after explaining them in detail about the drugs, objectives of the study, and the necessary procedures that they have to undergo during the trial. The clinical trial has also been registered in Clinical Trial Registry of India (CTRI/2014/08/004929).

Study Participants

A total of 100 confirmed cases of primary gouty arthritis fulfilling the diagnostic criteria as recommended by the American College of Rheumatology were selected for the present study from the outpatient department of the Central Ayurveda Research Institute for Respiratory Disorders, Patiala, and Regional Ayurveda Research Institute for Urinary Disorders, Jammu, India, irrespective of their sex, religion, and socioeconomic status. Patients were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol and were recruited in the study after obtaining written informed consent.

Inclusion Criteria

Patients of either sex aged between 25 and 65 years who presented themselves with at least 6 out of 12 criteria of American College of Rheumatology (1977), i.e., more than one attack of acute arthritis, maximal inflammation developing within 1 day of onset, monoarthritis attack, redness over affected joint, unilateral attack on the first metatasophalangeal (big toe) joint, unilateral attack involving tarsal joint, first metatasophalangeal (big toe) joint painful and swollen, suspected tophi, hyperuricemia (≥7.0 mg/dL), asymmetrical swelling within joint (X-ray), subcortical cysts without erosions (X-ray), negative culture from join fluid during attack, and those were willing and able to participate in the study for 14 weeks.

Exclusion Criteria

Patients with history of any trauma/fractured joint/surgical/diagnostic intervention with reference to the

affected joint(s); patients with comorbidities, such as rheumatoid arthritis, psoriatic arthritis, etc.; patients with poorly controlled hypertension (≥160/100 mm Hg); patients with poorly controlled diabetes mellitus (hemoglobin A1c ≥ 8.0%); patients with evidence of malignancy; patients with unstable cardiovascular disease; known cases of hypothyroidism or hyperthyroidism; patients with any concurrent hepatic disorder [defined as liver enzymes serum glutamic oxaloacetic transaminase/ serum glutamic pyruvic transaminase (SGOT/SGPT) > 2 times upper normal limit] or renal disorders (defined as serum creatinine >1.4 mg/dL) or severe chronic obstructive pulmonary disease; alcoholics/drug abusers; history of hypersensitivity to any of the trial drugs or their ingredients; pregnant/lactating woman; and any other condition which the Principal Investigator thinks may jeopardize the study.

Outcome Measures

Primary outcome measure was reduction in serum uric acid level from baseline to the end of 84th day. The secondary outcome measures were improvement in QOL using SF-36 (Research and Development) Health Survey Questionnaire, Patient's Global Assessment Scale, and Physician's Global Assessment Scale. The pain was assessed on Visual Analog Scale (VAS) score and the safety of the trial drug was assessed by laboratory parameters (liver and kidney function test) and occurrence of any adverse drug reaction/adverse event.

Study Interventions

The patients were administered *Amrita Guggulu* (Yoga Ratnakara; Vatarakta chikitsa, chapter 26; sloka no 59-65) in the dose of 1000 mg (2 tablets of 500 mg) twice daily with lukewarm water for a period of 12 weeks and Pinda Taila (Ayurvedic Formulary of India Part-I: Pg.140) in a dose of 10ml twice daily for local application on affected joint(s). .

Amrita Guggulu which is mentioned in the management of *Vatarakta* contains *Guduchi (Tinospora cordifolia),* Guggulu *(Commiphora mukul), Triphala (Terminalia chebula, Phyllanthus emblica and Terminalia bellerica),* Danti *(Baliospermum montanum),* Sunthi *(Zingiber officinale)* Marica *(Piper nigrum),* Pippali *(Piper longum),* Vidanga *(Embelia ribes),* Trivrt *(Operculina turpethum)* and Dalchini *(Cinnamomum zeylanicum).*

Pinda Taila consists mainly of ingredients like Beewax, Manjistha *(Rubia cordifolia),* Sarjarasa (oleoresin obtained from the tree *Vateria indica)* and Sariva (*Hemidesmus indicus*) which alleviates pain in Vatarakta by local application.

Both these quality assured Ayurvedic formulations were procured from Good Manufacturing Practice-certified Ayurvedic Pharmaceutical industries. After the end of treatment period of 12 weeks, patients were also followed without medications till 14th week.

Study Procedure

On the enrolment day at baseline (visit 1), patient's demographic profile, medical history, family history particularly related to *Vatarakta* vis-à-vis gout, sharirik prakriti, and vital parameters were recorded. Subsequent visits were planned at an interval of 2 weeks [14th day (visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (visit 5), 70th day (visit 6), and 84th day (visit 7)]. Patients were assessed and given study medications at each subsequent visit till 84th day. There was also a follow-up without medication after 2 weeks of 84th day visit, i.e., on 98th day. At the study site, data of all the patients were recorded in predesigned Case Report Forms (CRFs) and were also entered in electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The Xerox copies of the CRFs along with the e-CRFs of all enrolled patients were sent by all the participating centers to the Council's headquarters periodically for verification. Details of clinical assessment and study schedule are given in Flow Chart 1.

Statistical Analysis

Primary outcome and secondary outcome measures, i.e., serum uric acid level, QOL (SF-36 Health Survey score), pain assessment on VAS scale, were analyzed as mean change in the response from baseline to 84th day by using paired t-test. A p-value of <0.05 was considered significant. All statistical analysis was performed using Statistical Package for the Social Sciences version 15.0.

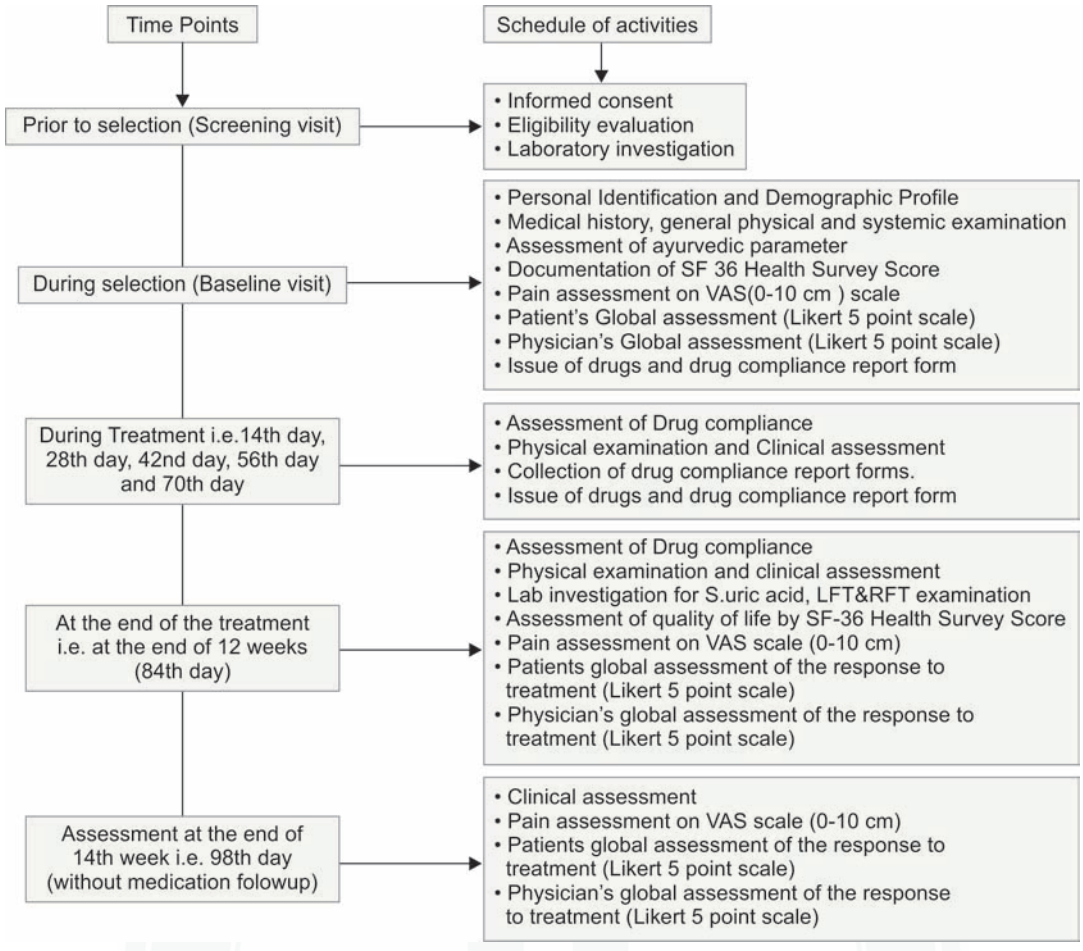
OBSERVATIONS AND RESULTS

Demographic Profile of the Patients

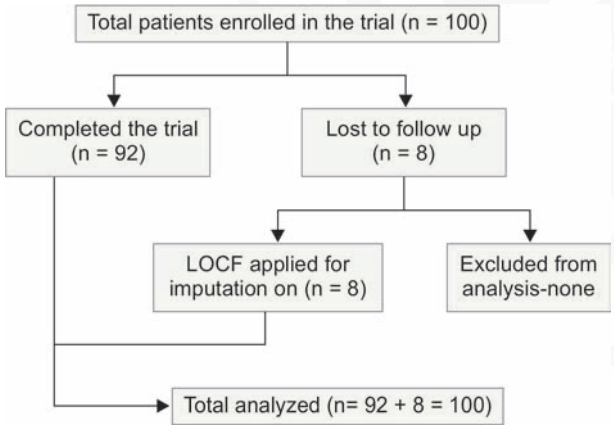
In the study, a total of 100 patients were enrolled, out of which 8 patients dropped out during the course of the study. Intention-to-treat analysis was done and the data of all those patients who have completed at least 14th day visit were imputed by last observation carried forward (LOCF) method. Hence, data of a total of 100 patients were used for statistical analysis. Flow Chart 2 shows the outflow of the patients in the study.

The demographic profile of 100 patients shows that the mean age of the patients was 47.55 years; 97% patients were married, 89% were literate, 92% were above poverty

Flow Chart 1: Study schedule; LFT: Liver function test; RFT: Renal function test



Flow Chart 2: Outflow of the patients in the study



line, 33% were desk workers. Table 1 shows the detailed demographic profile of the patients.

Effect of *Amrita Guggulu* and *Pinda Taila* on Clinical Features of Gout

After 84 days of treatment with trial drugs *Amrita Guggulu* and *Pinda Taila,* improvement was observed in clinical features. The effect of trial medications *Amrita Guggulu* and *Pinda Taila* on the complaints faced by the patients suffering from gout (*Vatarakta*) is shown in Table 2.

Table 1: Demographic profile of the patients (n = 100)

Variables	*Mean (SD)*	*%*
Age (years)	47.55 (9.82)	
Gender		
Male		82
Female		18
Marital status		
Married		97
Unmarried		3
Educational status		
Illiterate		11
Read and write		89
Socioeconomic status		
Above poverty line		92
Below poverty line		8
Habitat		
Urban		54
Semiurban		13
Rural		33
Occupation		
Desk work		33.0
Business		10.0
Housewife		17.0
Fieldwork		28.0
Fieldwork with physical labor		11.0
Student		1.0

SD: Standard deviation

Table 2: Effect of the treatment on chief complaints (n = 100)

Presence of complaints	*Baseline (%)*	*84th day (%)*	*% of relief*	*Follow-up at 98th day*	*% of relief*
Pain in joint(s) (*Sandhi Shula*)	100.0	62.0	38	54.0	46
Piercing pain (*Toda*)	59.6	3.0	56.6	4.0	55.6
Swelling (*Sandhi Shotha*)	93.0	12.0	81	11.0	82
Tenderness	97.0	18.0	79	17.0	80
Burning sensation (*Daha*)	52.0	4.0	48	5.0	47
Redness/erythema	47.0	3.0	44	2.0	45
Warmth	40.0	2.0	38	1.0	39
Stiffness (*Stabdhata*)	60.0	23.0	37	22.0	38
Suppuration (*Paka*)	0	0	0	0	0
Hyperesthesia (*Sparshasahtava*)	9.0	1.0	8	2.0	7
Local color changes in skin (*Twak Vaivarnya*)	11.0	0	11	0	11
Tophi	1.0	1.0	0	1.0	0

Table 3: Effect of the trial drugs on outcome measures

Parameters (n = 100)	*Baseline mean ± (SD)*	*84th day mean ± (SD)*	*t-value*[$]	*p-value*
Serum uric acid (mg/dL)	7.76 (0.75)	6.50 (1.25)	11.02	<0.001
Pain (assessed by VAS)	5.28 (1.78)	1.51 (1.78)	17.84	<0.001
Quality of life (SF-36 health survey score)				
Physical functioning	54.35 (21.39)	84.15 (15.14)	12.27	<0.001
Role limitation due to physical health	25.00 (41.44)	88.75 (31.46)	12.55	<0.001
Limitation due to emotional problems	27.66 (41.85)	88.67 (31.51)	11.75	<0.001
Energy/fatigue	51.05 (14.04)	66.55 (12.34)	8.8	<0.001
Emotional well-being	62.40 (15.0)	71.24 (12.5)	5.21	<0.001
Social functioning	55.44 (22.55)	78.75 (17.81)	8.35	<0.001
Pain	53.15 (20.35)	79.65 (19.08)	10.3	<0.001
General health	45.60 (15.7)	67.90 (12.29)	11.81	<0.001

Effect of the Trial Drugs on Outcome Measures

Effect of Amrita Guggulu and Pinda Taila on Serum Uric Acid, VAS Score, and QOL in Patients of Gout

It was observed that mean serum uric acid at the baseline was 7.76 mg/dL and reduced to 6.5 mg/dL after trial period of 84 days, which is statistically significant ($p < 0.001$). The pain was assessed on VAS (0–10 cm). The mean VAS score at the baseline was 5.3 cm and it was reduced to 1.5 cm at the end of treatment period, i.e., 84th day, which is statistically significant ($p < 0.001$). *Amrita Guggulu* and *Pinda Taila* have also been found effective in improving the QOL of the patients as assessed by SF-36 health survey questionnaire. A statistically significant improvement in all the eight domains of SF-36 health survey questionnaire, viz., physical functioning, role limitations due to physical health, limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health, was observed ($p < 0.001$) (Table 3).

Effect of Amrita Guggulu and Pinda Taila on Patient's Global Assessment Scale Score (5-point Likert Scale) in Patients of Gout

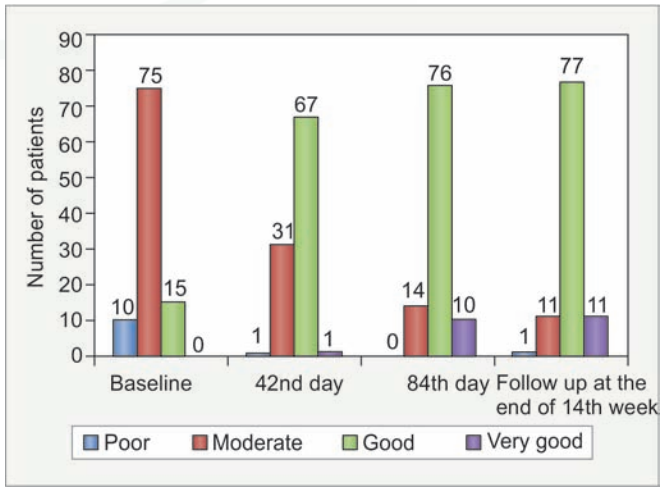
Significant improvement was observed on Patient's Global Assessment Scale score (5-point Likert scale) from the baseline to the end of treatment period, i.e., 84th day (Graph 1).

Effect of Amrita Guggulu and Pinda Taila on Physician's Global Assessment Scale Score (5-point Likert Scale) in Patients of Gout

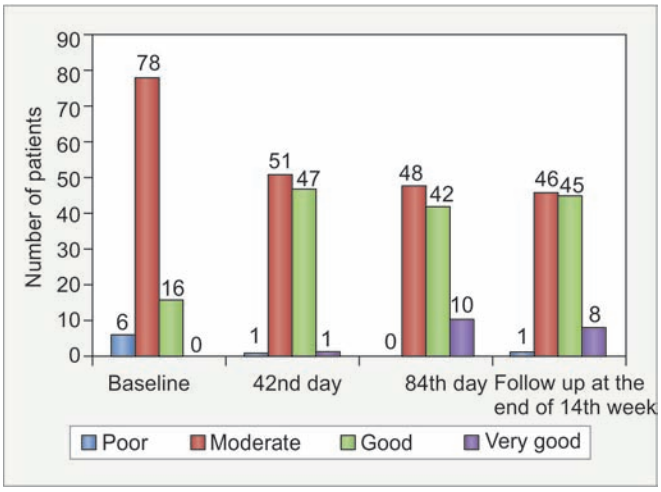
Significant improvement was observed on Physician's Global Assessment Scale score (5-point Likert scale) from the baseline to the end of treatment period, i.e., 84th day (Graph 2).

Effect of the Treatment on Safety Parameters

The laboratory safety parameters, viz., blood urea, serum creatinine, SGOT, and SGPT, were assessed at baseline



Graph 1: Effect of the trial drug on Patient's Global Assessment Scale

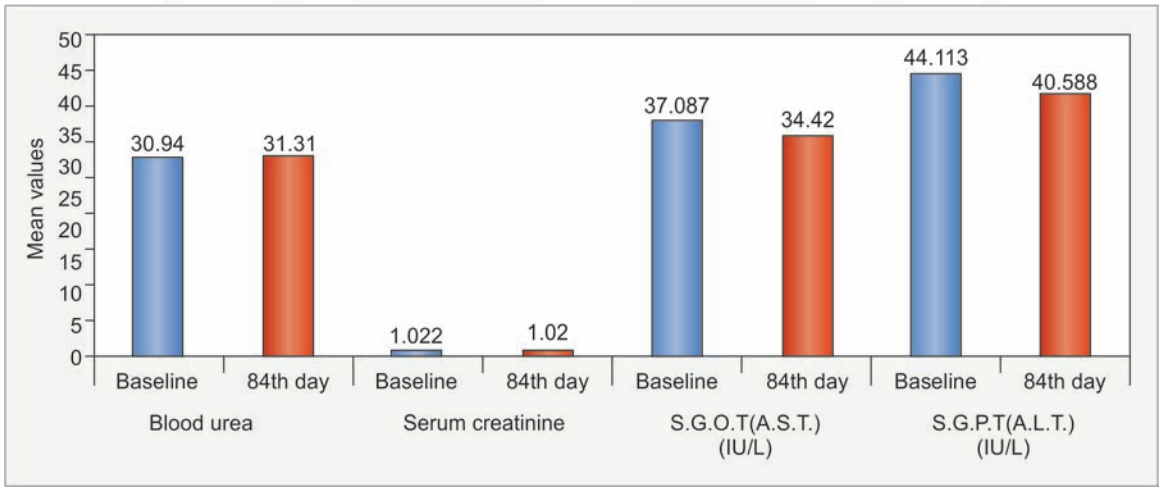


Graph 2: Effect of the trial drug on Physician's Global Assessment Scale

and at the end of treatment period (Graph 3). Though some changes were observed from the baseline to the end of the treatment, these were within the normal range. The details are given in Table 4.

DISCUSSION

Vatarakta viz-a-viz Gout has been recognized as a very painful form of acute and recurrent arthritis since antiquity and clear-cut descriptions of several disorders with symptoms of pain, inflammation and burning sensation in the joint are given in all medical books. Gout is caused by deposition of monosodium urate monohydrate (MSUM) crystals in joints and tissues, when serum uric acid levels exceed 6.8 mg/dl. It causes acute mono- or polyarticular arthritis as well as chronic inflammation, which leads to joint destruction. The stereotypical features of gouty arthritis are that urate crystals are directly activated with all of the major synovial cell types and result in the infiltration of neutrophils in both the inflamed joint fluid and the synovial membrane[5, 12, 13]. Activated neutrophils release proteolytic enzymes, free oxygen radicals, arachidonic metabolites and cytokines, which in turn bring about inflammation and tissue damage in acute gout[12, 14, 15]. It has been known that MSUM can regulate the expression of pro-inflammatory cytokines and help to propagate a local or systemic inflammatory process. Cytokines, such as tumour necrosis factor-alpha (TNF-α), interleukin-1beta (IL-1β), and interleukin-8 (IL-8), have been found in symptomatic joints of arthritic patients and have been implicated in acute gouty arthritic[11,16]. The goals of gouty arthritis treatment are anti-inflammatory therapy to manage the significant pain, swelling, and disability associated with acute attacks[17, 18]. The trial drugs *Amrita Guggulu* and *Pinda Taila* have proved to be anti-gout, anti-inflammatory and anti-hyperuricemic, as these combinations have produced statistically significant



Graph 3: Effect of the trial drug on safety parameters (blood urea, serum creatinine, SGOT, and SGPT)

Table 4: Effect of the treatment on safety parameters

Parameters (n = 100)	***Baseline Mean (SD)***	***84th day Mean (SD)***	***t-value$***	***p-value***
Blood urea	30.94 (7.308)	31.31 (6.810)	0.646	0.520
Serum creatinine	1.02 (0.142)	1.02 (0.147)	0.151	0.880
SGOT (IU/L)	37.08 (11.751)	34.42 (23.523)	1.093	0.277
SGPT (IU/L)	44.11 (15.492)	40.58 (16.452)	2.066	0.041
Urine R/E examination				
Volume	19.20 (10.468)	17.96 (9.716)	1.700	0.092
Specific gravity	1.020 (0.008)	1.020 (0.006)	0.105	0.917

SD: Standard deviation; $: Compared using paired t-test

improvement in the clinical manifestations, such as pain in joint(s) (*Sandhi Shula*), piercing pain (*Toda*), swelling (*Sandhi Shotha*), tenderness, burning sensation (*Daha*), redness/erythma(*raga*), warmth, stiffness (*Stabdhata*), hyperesthesia (*Sparshasahtava*) and local color changes in skin (*Twak Vaivarnya*), in the patients registered for the current trial along with reduction in marker of hyperuricemia i.e. serum uric acid. There was also decrease in the level of VAS score, patient's global assessment scale score and physician's global assessment scale score. There was no significant increase in liver function test (ALT & AST) and renal function test (blood urea and serum creatinine), indicating the safety profile of these drugs. There were no clinically significant adverse events, either reported or observed, during the entire study period. The components of the formulation *Amrita Guggulu* is having potent anti-inflammatory[19,20], analgesic, antipyretic[35], anti-arthritic activity[32], anti-mutagenic/anti-carcinogenic[28], hypolipidaemic and hypocholesterolemic activities[33,34] hepatoprotective[21,22], radio protective[23,24], anti-atherosclerotic [25,26], antiviral[27], antioxidant[29,30], and adaptogenic[31] properties, which are constitutive qualities for any drug to act against hyper-uricaemia induced inflammation. These activities might be mediated by inhibiting TNF-α, IL-1β, IL-8, and NF-κB p65 protein expression in synovial fluid and synovial tissue, and the suppression of NF-κB might be responsible for the decrease of the levels of IL-6, IL-8, and TNF-α in synovial tissue.

Ayurveda considers hyperuricemia under the spectrum of *Vatarakta* which is a disease caused by *avarana* of *rakta* on *vata* or viceversa. The management of *Vatarakta* is by removing the *margavarana* and clearing the *raktadushti*. Here the *rakta dushti* can be the causative factor for impairment in uric acid metabolism and its consequent deposition in the joints causing the symptoms of redness, joint pain, swelling etc. The components of *Amrita Guggulu* can be said to have uricosuric and anti inflammatory actions as is proven in this study as there was positive response in the outcome measures. Guggulu, a chief component of *Amrita Guggulu* has proven to have anti-inflammatory and anti oxidant properties.[36-38] *Amrita Guggulu* also has action on alleviating the symptoms caused by the hyper immune reaction triggered by uric acid deposition in joints. Guduchi is described as the best drug for the disease *Vatarakta* and it has actions on *rasavaha srotas* and *raktavaha srotas* and it improves circulation in the affected joints also. *Pinda Taila* is described in the context of *Vatarakta* as a potent pain reliever *(vatarakta rujapaha*). Abhyanga with *Pinda Taila* over the inflamed joints causes alterations in peripheral circulation and might augment the movement of accumulated inflammatory materials into the circulation and this correlates with *koshta gati* from *sakha*. *Pinda Taila* soothes *rakta* and *vata* simultaneously and reduces the inflammation and brings about changes in cardinal symptoms. The changes seen in this study after using this combination for a period of 84 days was statistically significant. The SF-36 health survey consists of eight scaled scores. The eight sections are: physical functioning, role limitations due to physical health, limitations due to emotional problems, energy / fatigue, emotional well being, social functioning, pain and general health. Lower the score, more the disability. The higher the score, lesser the disability i.e., a score of zero is equivalent to maximum disability and a score of 100 is equivalent to no disability. Increase in the score in physical functioning, role limitations due to physical health, limitations due to emotional problems, energy / fatigue, emotional well being, social functioning, pain and general health components of quality of life was observed after the completion of trial, which indicates improvement in the quality of life. Hence, it can be said that the simultaneous use of *Amrita Guggulu* internally and *Pinda Taila* externally has significant therapeutic efficacy while having the added advantage of being safe to use for a continued period of time.

CONCLUSION

Amrita Guggulu and *Pinda Taila* in the dosage of 1000 mg internally and 10 ml externally respectively, twice daily, produced significant response in relieving the symptoms of hyperuricemia and also in reducing the levels of serum uric acid. This combination can be said to have anti-inflammatory, anti-hyperuricemic and anti-oxidant activity. The combination of *Amrita Guggulu* and *Pinda Taila* has proven to be effective, safe and tolerable in patients with hyperuricemia in reducing the symptoms and improving the quality of life.

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सारांश

अमृता गुग्गुलु व पिण्ड तैल का वातरक्त के रोगियों के रक्त में यूरिक एसिड अधिक होने की चिकित्सा में प्रभावकारिता हेतु ओपेन लेबल अध्ययन

[1]हरबंस सिंह, [2]राजेश सण्ड, [3]लक्ष्मण वामन भुरके, [4]कृष्णा कुमारी, [5]रेनू सिंह, [6]एस के वेदी, [7]आदर्श कुमार, [8]भारती, [9]राकेश राणा, [10]ऋचा सिंघल [11]एन श्रीकांत, [12]एम एम पाढ़ी, [13]करतार सिंह धीमान

पृष्ठभूमिः वातरक्त अर्थात गाउट सामान्य एंव विशिष्ट चिकित्सा दोनों में एक सामान्य अवस्था है। वातरक्त एक तंत्रगत व्याधि है जो कि रक्त में यूरिकएसिड की मात्रा में बढोतरी के लक्षणों द्वारा परिलक्षित होती है, जिसके परिणाम स्वरूप मोनोसोडियम युरेट के क्रिस्टल विभिन्न कोशिकाओं में जमा हो जाते हैं। क्रिस्टल आर्थराइटिस में गाउट सबसे सामान्य है, जो कि यूरिक एसिड चयापचय के बाधित होने तथा संधियों के बाह्य कोशिकीय स्थानों, पेरिआर्टिकुलर उत्तको, अस्थियों तथा अन्य अवयवों में युरेट क्रिस्टल के जमा हो जाने के परिणाम स्वरूप होता है।

उद्देश्यः अमृता गुग्गुलु एंव पिण्ड तैल का वातरक्त से ग्रसित 100 रोगियों पर इसके प्रभाव एंव निरापदता का अध्ययन।

सामग्री एंव विधिः वर्तमान अध्ययन के लिए अमेरिकन कॉलेज ऑफ रियुमेटोलोजी के द्वारा संधिवात/वातरक्त के लिए सुझाये ग्ए/निर्धारित नैदानिक मानदंडो को पूरा करने वाले प्राथमिक वातरक्तीय संधिवात (गठिया) के कुल 100 रोगियों (25 से 65 वर्ष के मध्य) का चयन सीएआरआईआरडी पटियाला तथा आरएआरआईयूडी जम्मू के बहिरंग रोगी विभाग से उनके लिंग, धर्म तथा सामाजिक–आर्थिक स्थिति से निरपेक्ष रहते हुए किया गया। नैदानिक परीक्षण के लिए केवल उन रोगियों का चयन किया गया जो अमेरिकन कॉलेज ऑफ रियुमेटोलोजी द्वारा वातरक्त के लिए निर्धारित 12 मे से कम से कम 6 मानदंडों को पूरा करते हों। रोगियों को अमृता गुग्गुलु 1000 मि.ग्रा. दिन में दो बार खाने के लिए तथा 10 मि.ली. पिण्ड तेल दिन में दो बार स्थानिक अभ्यंगार्थ दिया गया।

परिणामः परीक्षण चिकित्सा का मूल्यांकन नैदानिक लक्षणों में सुधार, वी.ए.एस. स्कोर, पेशेन्ट ग्लोबल असेसमेन्ट स्केल स्कोर, फिजिसियन्ज़ ग्लोबल असेसमेन्ट स्केल स्कोर, तथा जैव–रसायनिक मापदण्ड के आधार पर किया गया। यह अध्ययन प्रत्येक रोगी पर तीन माह के लिए किया गया तथा इन योगों द्वारा रक्त में यूरिक एसिड की कमी देखने के लिए तथा इनके निरापद होने के लिए उपचार के आरम्भ में, 28वें दिन तथा 84वें दिन रक्त परीक्षण किए गए जिनमें मुख्यतः सीरम यूरिक एसिड, यकृत कार्य परीक्षण (एल.एफ.टी), वृक्क कार्य परीक्षण (के.एफ.टी.) शामिल हैं। रोगियों के जीवन स्तर का अनुमान करने के लिए एस.एफ.–36 स्वास्थ्य सर्वेक्षण स्कोर का अनुसरण किया गया। उपचार परीक्षण योग से नैदानिक लक्षणों में महत्वपूर्ण सुधार दिखाई दिए तथा साथ की सीरम यूरिक एसिड के स्तर में भी कमी आई, जिसका आधार स्तर उपचार शुरू करने से पूर्व 7.76 मि.ग्रा./डे.ली. था जो उपचार के 84वें दिन घटकर 6.50 मि.ग्रा./डे.ली. हो गया। इसके अतिरिक्त वेदना की जाँच के लिए वी.ए.एस. स्केल स्कोर में भी कमी आई तथा यकृत एवं वृक्क कार्य परीक्षण में भी कोई हानिकारक परिवर्तन नहीं हुए जो कि इस चिकित्सा की निरापदता सिद्ध करते है।

निष्कर्षः इस प्रकार यह निष्कर्ष निकाला जा सकता है कि अमृता गुग्गुलु और पिण्ड तेल वातरक्त के रोगियों के लिए सुरक्षित एंव प्रभावी चिकित्सा है।