Original Article

An open-label prospective observational trial for assessing the effect of homoeopathic medicines in patients suffering from gout

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Abstract

Background: Gout is an inflammatory arthritis associated with hyperuricaemia and intra-articular monosodium urate crystals, resulting in pain, activity limitation, disability and impact on patients' quality of life. **Objective:** The objective of this study was to examine the effects of individualised homoeopathic medicines in serum uric acid level and quality of life in patients suffering from gout. **Methods:** A prospective, single-arm, non-randomised, open-label, observational trial was conducted on 32 adults suffering from gout (diagnosed as per the American College of Rheumatology–European League Against Rheumatism gout classification criteria) at the Outpatient Department of The Calcutta Homoeopathic Medical College and Hospital, Kolkata. Serum uric acid level was the primary outcome (baseline vs. 3 months); Gout Assessment Questionnaire v2.0 (GAQ2; baseline vs. 3 months) and Measure Yourself Medical Outcome Profile v2.0 (MYMOP2; baseline, every month and up to 3 months) were the secondary outcomes. Intention-to-treat sample (n = 32) was analysed in SPSS®IBM® version 20. **Results:** The mean age of patients was 47.6 years; the male: female ratio was 5:3. Both serum uric acid level (mg/dl) (7.6 ± 1.4 vs. 6.0 ± 1.5; mean reduction: 1.6, 95% confidence interval [CI] = 1.1, 2.1, $P < 0.001$, Student's t-test) and GAQ2 total score (45.0 ± 9.1 vs. 21.0 ± 14.0; mean reduction: 24.0, 95% CI 19.1, 29.0, $P < 0.001$, Student's t-test) reduced significantly over 3 months. MYMOP2 scores obtained longitudinally at four different time points also revealed statistically significant reductions ($P < 0.001$, one-way repeated measures ANOVA). The most frequently indicated medicine was *Benzoicum acidum*. **Conclusion:** This study, though preliminary, revealed a positive treatment effect of individualised homoeopathic medicines in alleviating the symptoms of gout and improving the quality of life. More studies like randomised controlled trials with greater scientific rigour are warranted.

Keywords: American College of Rheumatology–European League against Rheumatism, Gout, Gout Assessment Questionnaire v2.0, Gout classification criteria, Homoeopathy, Measure Yourself Medical Outcome Profile v2.0

Introduction

Gout is an inflammatory arthritis associated with hyperuricaemia and intra-articular sodium urate crystals resulting in painful joint inflammation (arthritis). The prevalence of gout has increased substantially in the past two decades to 2.5% in the UK.[1] and 3.9% in the USA.[2] Modernisation and affluence on lifestyle, including decreased physical activity, increased consumption of foods rich in purine, fructose and alcoholic beverages and smoking, have been shown to contribute to hyperuricaemia resulting in gout,[3] and thus, developed countries tend to have a higher burden of gout than developing countries. Its incidence is 2–6 fold higher in men than in women. The prevalence of gout in India is 0.12% as per the International League of Nations against Rheumatism, Community Oriented Program for Control of Rheumatic Diseases.[4]

The presence of monosodium urate (MSU) monohydrate crystals in a symptomatic joint/bursa (i.e. synovial fluid) or in a tophus is a sufficient criterion for the diagnosis of gout, and does not require further scoring, but its use is often

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restricted to secondary and tertiary care centres. Identification of MSU crystals in a primary care setting is usually not feasible as it requires both expertise in joint puncture and expensive equipment those are not readily accessible. In patients suffering from acute arthritis and in whom synovial fluid analysis is difficult, the diagnosis of gout flare should be based on certain suggestive clinical features and the serum uric acid level in a primary care setting.[5] The 2015 American College of Rheumatology–European League Against Rheumatism (ACR-EULAR gout classification criteria[6,7] is a standardised and highly specific approach to identify relatively homogeneous group of individuals who have the clinical entity of gout in a primary care setup. The entry criterion requires the occurrence of at least 1 (one) episode of peripheral joint or bursal swelling, pain or tenderness. The domains of this criterion include clinical (pattern of joint/bursa involvement, characteristics and time course of symptomatic episodes), laboratory (serum urate and MSU-negative synovial fluid aspirate) and imaging (double contour sign on ultrasound or urate on dual-energy computed tomography and radiographic gout-related erosion).

PubMed search revealed total 17,736 studies on gout, of which only five used the Gout Assessment Questionnaire (GAQ) and only three studies[8-10] used Homoeopathy. However, no study result could be elucidated with GAQ2, Measure Yourself Medical Outcome Profile v2.0 (MYMOP2) and Homoeopathy. As per AYUSH Research Portal, total 21 clinical research works on gout under AYUSH system were carried out, but of those, only one was with Homoeopathy. It was a qualitative study in which ten individuals presented themselves within 5 days of the onset of acute gout and participated in a 15-day study period. Serum uric acid levels were tested on day 1 and day 6 to assess hyperuricaemia. Treatment effect was evaluated on days 1, 3 and 6 based on day subjective. This single-arm, open-label study generated some promising results in favour of Homoeopathy in treatment of acute gout within 6 days, but due to its obvious methodological shortcomings, the results can be considered as preliminary only.[11] Thus, literature on homoeopathic medicines in the treatment of gout with improvement in the quality of life remains insufficient. As the existing evidences remain miniscule, at the very first attempt, we aimed to generate some preliminary data about any possible effects of Homoeopathy in gout in pre–post comparison design, to be subjected to explanatory robust trials in future.

Methods

Setting and design

A prospective, single-arm, non-randomised, open-label, observational trial was conducted from November 2017 to April 2018 on 32 adult individuals suffering from gout (as per the ACR-EULAR gout classification criteria) at the Outpatient Department of The Calcutta Homoeopathic Medical College and Hospital (CHMC and H), Kolkata. The proposed plan of work adhered to the ethical guidelines of the Declaration of Helsinki[12] and was approved by the Ethical Committee of the institution (CHMCH/IEC/13/2018, dated 05 January 2018) retrospectively. The trial could not, however, be registered with the Clinical Trials Registry of India due to a retrospective approval of the Ethical Committee. Each patient was provided with a patient information sheet in local vernacular Bengali language detailing the objectives, methods, risks and benefits of participating and confidentiality issues. Before enrolment, written informed consent was taken from the patients.

Inclusion and exclusion criteria

Individuals of either of the sexes of age 18 years and above, who had scored 8 or more in the 2015 ACR-EULAR gout classification criteria, having no unstable psychiatric illness or other systemic disease and who have not used any medication in the past 1 month were enrolled. Patients who did not give consent were excluded. Case taking was done for each patient in accordance with the standardized homoeopathic principles. Cases with manifestation of causes for secondary gout were ruled out. All the cases were diagnosed only on the basis of serum uric acid and clinical assessment. Radiological or synovial fluid examination was not done, as those were not available at the institution. Patients with score more than or equal to 8 were included, without the score of the said two examinations.

Outcome assessment

- Primary outcome – Serum uric acid level (baseline vs. 3 months)
- Secondary outcomes – GAQ2[13] (baseline vs. 3 months) and MYMOP2[14] (baseline, every month and up to 3 months).

All outcomes were recorded in pre-designed follow-up forms; influence of gout on health-related quality of life of patients was assessed through GAQ2 measured at baseline and at the 3rd month. GAQ2 is a disease-specific patient-reported outcome measure with 24 items, consisting of 5 different subscales: gout concern overall, gout medication side effects, well-being during attack, unmet gout treatment needs and gout concern during attack. Each item of the GAQ2 is rated 'strongly agree' to 'strongly disagree', 'all of the time' to 'none of the time' or 'not a bit' to 'extremely' on a 5-point Likert scale. A higher score denotes a greater impact of disease. It has five domains: gout concern overall, gout medication side effects, well-being during attack, unmet gout treatment needs and gout concern during attack.

Patients' responses were assessed through MYMOP2 initial and follow-up forms, measured and analysed at baseline, after the 1st, 2nd and 3rd months. The most troublesome symptom of gout in each case was recorded as Symptom 1, the intensity of which was marked by a patient on a 7-point scale (from 0 to 6, 0 = as good as it can be and 6 = as bad as it can be); simultaneously, activity, well-being of the individual and other associated symptom in each case was recorded as Symptom 2 and the intensity was scored. Patients presented with pain in heels, pain in knee, pain in toes and swelling of toe with pain as Symptom 1, and as Symptom 2, the participants

presented with varied ailments like gastrointestinal complaints such as bleeding per rectum, constipation, bloated abdomen and mucoid stool; urinary complaints such as scanty urine, burning in micturition and offensive urine and sleeplessness.

Intervention and follow-up

All patients were given appropriate individualised homoeopathic medicines based on homoeopathic principles. Patients were advised to take care of their lifestyle by altering the diet and regimen. Cases were repertorized if required. Repetition was done depending on the individual requirement of the cases. Each patient enrolled was intervened for a period of 3 months, and follow-up was conducted at least once a month or earlier, as required by the patient.

Statistical analysis

Both descriptive and inferential statistics were used. Intention-to-treat sample was subjected to statistical analysis. Missing values were replaced by last value carried forward method. Student's *t*-test and one-way repeated measures ANOVA were used keeping $P < 0.05$ two-tailed as statistically significant. Statistical Package for the Social Sciences, version 20.0 (IBM Corp., IBM SPSS Statistics for Windows, Armonk, NY: USA) was used for analysis.

Results

Study flow

A total of 55 patients were preliminarily screened on the basis of entry criterion of occurrence of at least one episode of peripheral joint or bursal swelling, pain or tenderness and serum uric acid level. Of which, 45 were assessed for eligibility. No patient underwent radiological examination or synovial fluid examination, as they were not available at the institution. The ACR-EULAR gout score was <8 in 9 patients and 4 did not give consent. Hence, only 32 patients could be enrolled in the study after screening them according to the inclusion and exclusion criteria [Figure 1].

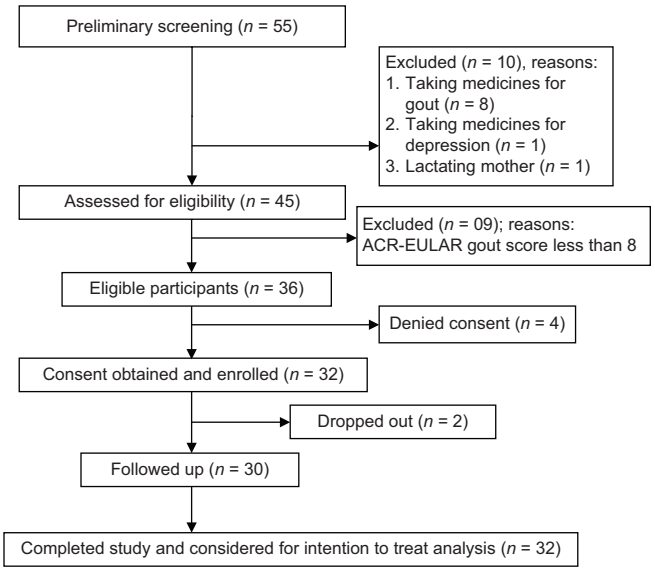

Figure 1: Study flow diagram

Baseline features

The maximum number of patients belonged to the age group of 31–40 years ($n = 11$; 34.4%) and 41–50 years ($n = 11$; 34.4%), followed by 51–60 years ($n = 7$; 21.9%) [Table 1]. Male patients were the majority ($n = 20$; 62.5%). Further, 65.6% ($n = 21$) of the patients had mixed type of diet, 9 patients (28.1%) had regular smoking habit, 1 patient had a habit of regular consumption of alcohol and 11 patients (34.4%) occasionally took alcohol. Dietary habit of intake of red meat regularly was presented in 9.4% ($n = 3$) patients, whereas 37.5% ($n = 12$) of the patients occasionally consumed red meat and 21 (65.6%) patients occasionally consumed soft drinks [Table 2]. The mean ACR–EULAR gout score was 8.2, with 62.5% ($n = 20$) having a score of 8 and 34.4% ($n = 11$) with score of 11. None of the patients were with score 12 and above [Table 2].

The other comorbid conditions recorded in Symptom 2 of MYMOP2 were– gastrointestinal complaints (6 patients), haemorrhoids with bleeding per rectum (2 patients), constipation (1 patient), mucoid stool (1 patient), cough, sleeplessness in 2 patients, urinary complaints in 4 patients, scanty menses with engorgement of breast before menses in one patient and warm sensation, wet sensation, itching, burning sensation on legs, chronic intertrigo and otorrhoea in one patient each.

Table 1: Sociodemographic profile of the patients ($n=32$)

Characteristics	Estimates
Age (years)[#], mean±SD	47.6±11.3
Sex[§], *n* (%)	
Male	20 (62.5)
Female	12 (37.5)
Economic status[§], *n* (%)	
Lower	2 (6.3)
Middle	28 (87.5)
Upper	2 (6.3)
Marital status[§], *n* (%)	
Married	29 (90.6)
Others	3 (9.4)
Residence[§], *n* (%)	
Urban	16 (50)
Semi-urban	9 (28.1)
Rural	7 (21.9)
Duration of suffering[§], *n* (%)	
0-4 weeks	8 (25)
4-12 weeks	3 (9.4)
3 months-1 year	14 (43.8)
1-5 years	7 (21.9)

[#]Data presented as mean±SD, [§]Categorical data presented as absolute values (%). SD: Standard deviation

Symptom profile

Among the total 32 patients enrolled for the study, 2 patients presented with classical acute gout, i.e. sudden development of a painful, swollen, warm metatarsophalangeal joint, whereas 7 patients had involvement of monoarticular joint and rest of the 23 patients had polyarticular joint involvement.

Pre–post comparison

Among the 32 patients, only one patient had an increase of uric acid level after 3 months' follow-up and two dropped out of the study. The uric acid level reduced from 6.70 mg/dl to 5.48 mg/dl and 8.15 mg/dl to 6.32 mg/dl in female and male patients, respectively, after 3 months of treatment. Both serum uric acid level (mg/dl) (7.6 ± 1.4 vs. 6.0 ± 1.5; mean reduction: 1.6, 95% confidence interval [CI] = 1.1, 2.1, $P < 0.001$, Student's *t*-test) and GAQ2 total score (45.0 ± 9.1 vs. 21.0 ± 14.0; mean reduction: 24.0, 95% CI = 19.1, 29.0, $P < 0.001$, Student's *t*-test) reduced significantly over 3 months [Table 3]. The pre-medication mean score of concern of gout medication side effects reduced from 4.7 to 1.6 after 3 months of treatment, whereas the mean score of concern of well-being during attack reduced from 19.3 to 9.5 and after medication gout concern during attack reduced from 8.1 to 3.9 [Table 3]. The mean pain intensity score of MYMOP2 (Symptom 1) improved from 5.2 (baseline) to 4.3 (at the 1st month), 3.8 (at the 2nd month) and finally 3 (at the 3rd month). The mean activity score improved from 4.8 (baseline) to 3.9 (at the 1st month), 3.5 (at the 2nd month) and finally 2.7 (at the 3rd month) after medication. The mean well-being score of the patients with gout also improved from 5.1 (baseline) to 4.1 (at the 1st month), 3.5 (at the 2nd month) and finally 2.5 (at the 3rd month). A significant improvement in the mean intensity score of associated symptom in each case (recorded as Symptom 2) was changed from 3.9 at baseline to 1.6 after the 3rd month [Table 4].

Table 2: Eating habit and predisposing factors of the patients (n=32)

Features	Estimates
Diet§, *n* (%)	
Vegetarian	3 (9.4)
Non-vegetarian	8 (25.0)
Mixed	21 (65.6)
Smoking habit§, *n* (%)	
Never	15 (46.9)
Quit	4 (12.5)
Occasional	4 (12.5)
Regular	9 (28.1)
Alcohol intake§, *n* (%)	
Never	18 (56.3)
Quit	2 (6.3)
Occasional	11 (34.4)
Regular	1 (3.1)
Red meat intake§, *n* (%)	
Never	13 (40.6)
Quit	4 (12.5)
Occasional	12 (37.5)
Regular	3 (9.4)
Seafood intake§, *n* (%)	
Never	6 (18.8)
Quit	2 (6.3)
Occasional	23 (71.9)
Regular	1 (3.1)
Soft drink intake§, *n* (%)	
Never	7 (21.9)
Occasional	21 (65.6)
Regular	4 12.5)
Exercise§, *n* (%)	
Never	19 (59.4)
Occasional	10 (31.3)
Regular	3 (9.4)
Family history of hyperuricaemia§, *n* (%)	
None	23 (71.9)
Maternal	4 (12.5)
Paternal	4 (12.5)
Both	1 (3.1)
Serum uric acid level#, mean±SD	
Male	8.2±1.4
Female	6.7±0.7
ACR-EULAR score#, mean±SD	8.5±0.8

#Data presented as mean±SD, §Categorical data presented as absolute values (%). SD: Standard deviation, ACR-EULAR: American College of Rheumatology-European League against Rheumatism

Homoeopathic medicines used

As per the totality of symptoms, at the baseline, *Benzoicum acidum* was prescribed in 8 patients (25%) and *Lachesis mutus*, *Lycopodium clavatum*, *Pulsatilla nigricans* and *Rhus toxicodendron* were prescribed in 3 patients (9.4%) each. In the subsequent prescriptions also, *Benzoicum acidum* was the most frequently used medicine, followed by *Colchicum autumnale*. The indicated medicines were prescribed in different potencies as per the susceptibility of each individual patient and guidelines of the Organon of Medicine. Medicines were changed as per the demand of each case, when there was no such marked improvement or totality of symptoms changed. Placebo was prescribed as long as improvement continued. Among the 32 patients, no change of medicine was required for 18 patients, though repetition or prescription of higher potencies was prescribed when cases came to a standstill and the same potency was not enough to cure the case. The lists of prescribed medicines and the indications of the most frequently prescribed remedies are given in Tables 5 and 6, respectively.

Discussion

Compared to baseline, serum uric acid, GAQ2 and MYMOP2 scores of participants reduced significantly over three months. As per the totality of symptoms, twenty different homoeopathic medicines were used, *Benzoicum acidum* being the most common.

It was observed that many associated symptoms of the patient, such as acidity, sleeplessness, bleeding per rectum, constipation, cough and itching (MYMOP2, Symptom 2), improved, suggesting Homoeopathy as a holistic care therapeutic method. This study elicited the potential effect of individualised homoeopathic medicines in not only reducing the serum uric acid but also improvement in activity and well-being of patients with gout, without any substantial medicinal adverse effects. The methodological strengths of the study were its prospective design, use of validated questionnaires, such as

GAQ2 and MYMOP2, treatment by qualified and experienced homoeopathic physicians schooled in and practicing classical Homoeopathy in dealing with a challenging condition like gout – a single, simple medicine in minimum dose based on totality of symptoms in each individual case. No such published homoeopathic studies on gout could be identified to compare the findings of MYMOP2. The single published study[8] was an open-label, single-arm trial involving only ten individuals who presented within 5 days of the onset of acute gout. Three outcome measures were used – serum uric acid level, joint improvement score and Ritchie's score of joint swelling and joint tenderness – all assessed on days 1, 3 and

Table 3: Comparison of outcome measures at baseline and after 3 months by paired *t*-test

Outcomes	Mean±SD			t_{31} score	*P*
	Baseline	Month 3	Change 0-3 (95% CI)		
Serum uric acid	7.6±1.4	6.0±1.5	1.6±1.3 (1.1-2.1)	7.208	<0.001*
GAQ2 scores					
Total	45.0±9.1	21.0±14.0	24.0±13.7 (19.1-29.0)	9.955	<0.001*
Concern overall	13.0±2.1	6.0±4.3	7.0±4.5 (5.4-8.6)	8.770	<0.001*
Medication side effects	4.7±1.5	1.6±1.5	3.1±1.8 (2.4-3.7)	9.464	<0.001*
Well-being during attack	19.3±5.7	9.5±6.8	9.8±6.6 (7.4-12.2)	8.347	<0.001*
Concern during attack	8.1±2.8	3.9±2.8	4.2±3.4 (2.9-5.4)	7.015	<0.001*

GAQ2: Gout Assessment Questionnaire v2.0, SD: Standard deviation, CI: Confidence interval

Table 4: Changes in repeatedly Measure Yourself Medical Outcome Profile v2.0 over 3 months

MYMOP2 scores	Mean±SD							*P*
	Baseline	Month 1	Month 2	Month 3	Change 0-1 (95% CI)	Change 0-2 (95% CI)	Change 0-3 (95% CI)	
Pain intensity	5.2±0.9	4.3±1.1	3.8±1.3	3.0±1.5	0.8±0.9 (0.5-1.2)*	1.3±1.1 (0.9-1.7)**	2.2±1.4 (1.7-2.7)***	<0.001****
Activity score	4.8±1.2	3.9±1.3	3.5±1.3	2.7±1.5	0.8±1.1 (0.5-1.2)$^{\#}$	1.3±1.1 (0.8-1.7)$^{\#\#}$	2.1±1.6 (1.5-2.7)$^{\#\#\#}$	<0.001$^{\#\#\#\#}$
Well-being score	5.1±1.0	4.1±0.9	3.5±1.0	2.5±1.4	0.9±0.9 (0.6-1.3)$^{¥}$	1.5±1.2 (1.1-2.0)$^{¥¥}$	2.6±1.5 (2.0-3.1)$^{¥¥¥}$	<0.001$^{¥¥¥¥}$
Symptom 2 intensity	3.9±0.9	3.0±0.7	2.4±0.9	1.6±1.3	0.9±0.8 (0.6-1.2)$^{\Psi}$	1.5±0.9 (1.2-1.8)$^{\Psi\Psi}$	2.3±1.3 (1.8-2.7)$^{\Psi\Psi\Psi}$	<0.001$^{\Psi\Psi\Psi\Psi}$

*t_{31}=5.400, *P*<0.001, **t_{31}=6.466, *P*<0.001, ***t_{31}=8.752, *P*<0.001 (pairwise comparison using paired *t*-test), ****Wilks' λ=0.278, F_3, 29=25.112, partial η^2=0.722 (One-way repeated measures ANOVA), $^{\#}t_{31}$=4.543, *P*<0.001, $^{\#\#}t_{31}$=6.225, *P*<0.001, $^{\#\#\#}t_{31}$=7.629, *P*<0.001 (pairwise comparison using paired *t*-test), $^{\#\#\#\#}$Wilks' λ=0.346, F_3, 29=18.291, partial η^2=0.654 (One-way repeated measures ANOVA), $^{¥}t_{31}$=5.593, *P*<0.001, $^{¥¥}t_{31}$=7.314, *P*<0.001, $^{¥¥¥}t_{31}$=9.655, *P*<0.001 (pairwise comparison using paired *t*-test), $^{¥¥¥¥}$Wilks' λ=0.252, F_3, 29=27.641, partial η^2=0.748 (One-way repeated measures ANOVA), $^{\Psi}t_{31}$=6.241, *P*<0.001, $^{\Psi\Psi}t_{31}$=9.644, *P*<0.001, $^{\Psi\Psi\Psi}t_{31}$=10.114, *P*<0.001 (pairwise comparison using paired *t*-test), $^{\Psi\Psi\Psi\Psi}$Wilks' λ=0.201, F_3, 29=38.544, partial η^2=0.799 (One-way repeated measures ANOVA). MYMOP2: Measure Yourself Medical Outcome Profile v2.0, SD: Standard deviation, CI: Confidence interval

Table 5: Medicines prescribed during the study

Medicine prescribed at baseline	Medicine prescribed at the end of the 1st month	Medicine prescribed at the end of the 2nd month	Medicine prescribed at the end of the 3rd month
Apis mellifica (*n*=1)	*Benzoicum acidum* (*n*=6)	*Benzoicum acidum* (*n*=5)	*Benzoicum acidum* (*n*=3)
Benzoicum acidum (*n*=8)	*Calcarea phosphorica* (*n*=1)	*Calcarea phosphorica* (*n*=2)	*Calcarea phosphorica* (*n*=1)
Calcarea phosphorica (*n*=1)	*Causticum* (*n*=1)	*Colchicum autumnale* (*n*=2)	*Causticum* (*n*=2)
Causticum (*n*=1)	*Colchicum autumnale* (*n*=3)	*Kalium carbonicum* (*n*=1)	*Colchicum autumnale* (*n*=1)
Colchicum autumnale (*n*=1)	*Kalium carbonicum* (*n*=1)	*Ledum palustre* (*n*=1)	*Lachesis mutus* (*n*=1)
Kalium carbonicum (*n*=1)	*Ledum palustre* (*n*=1)	*Lycopodium clavatum* (*n*=2)	*Natrum sulphuricum* (*n*=1)
Lachesis mutus (*n*=3)	*Medorrhinum* (*n*=1)	*Natrum muriaticum* (*n*=1)	Placebo (*n*=21)
Ledum palustre (*n*=1)	*Natrum sulphuricum* (*n*=1)	*Sepia officinalis* (*n*=1)	
Lycopodium clavatum (*n*=3)	*Pulsatilla nigricans* (*n*=2)	*Colchicum autumnale* (*n*=1)	
Mercurius solubilis (*n*=1)	*Thuja occidentalis* (*n*=1)	*Urtica urens* (*n*=1)	
Natrum sulphuricum (*n*=1)	*Urtica urens* (*n*=3)	Placebo (*n*=13)	
Nux vomica (*n*=1)	Placebo (*n*=10)		
Pulsatilla nigricans (*n*=3)			
Rhus toxicodendron (*n*=3)			
Sulphur (*n*=1)			
Thuja occidentalis (*n*=1)			
Urtica urens (*n*=1)			

Table 6: Indications of the most frequently prescribed medicines

Medicines	Indications
Benzoicum acidum	Tearing, stitching pain in toe, aggravated at night, open air with strong smelling urine
Lachesis mutus	Swelling in knee aggravated after walking, sharp agonising pain with red or bluish painful swelling in climacteric age
Lycopodium clavatum	Swelling of the legs, toes with red, burning spots, pain ameliorated by walking in open air, nocturnal pain with numbness associated with bloating, flatulence, constipation, etc.
Pulsatilla nigricans	Red hot swelling of foot with heaviness, pain associated with chill, aggravated in the evening, allowing the feet to hang down, with flatulence, and thirstlessness
Rhus toxicodendron	Arthritic nodosities, tearing, aching pain aggravated by initial motion, damp weather and ameliorated by continued motion, warm application
Colchicum autumnale	Shifting rheumatism, pain goes from left to right, inflammation of great toe, cannot bear to be touched, aggravated in change of weather, nausea and appetite lost from smell of food

6. All the acute symptoms of gout were found to be resolved within a span of 6 days only. Among the used medicines, *Benzoic acid, Causticum, Rhus toxicodendron, Ledum palustre, Colchicum autumnale* and *Calcarea carbonica* were common. The findings were preliminary only and further studies were warranted. The period of study was, however less to evaluate the effect of treatment in reducing the progress of the disease and in preventing acute attacks. In the absence of control arm, there is always chance of overestimation of treatment effect sizes. In comparison, our study was better than this in terms of number of patients, use of validated questionnaires as secondary outcomes, longer duration of follow-ups and comparatively rigorous statistical analysis. Adequately powered randomised controlled trials are warranted to arrive at a definite conclusion regarding the efficacy of homoeopathic medicines in gout.

Conclusion

Homoeopathic management has adequate potential in not only alleviating the serum uric acid in gout but also a significant role in improving the well-being, activity and quality of life of patients with gout, without any adverse effects. This prospective observational trial, though preliminary, revealed a positive treatment effect of homoeopathic medicines in gout. The study findings need to be interpreted with caution and further be experimented in randomised placebo-controlled design with enhanced methodological rigor and longer follow-up.

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Conflicts of interest

None declared.

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गाउट से पीड़ित रोगियों में होम्योपैथिक दवाओं के प्रभाव का आंकलन करने के लिए एक संभावित अवलोकन परीक्षण।

पृष्ठभूमि : गठिया एक सूजन युक्त जोड़ों का दर्द है जो हाइपर्यूरिमिया से जुड़ा होता है और इंट्रा–आर्टिकुलर मोनो सोडियम यूरेट क्रिस्टल (एमएसयू) के चित्रण के परिणामस्वरुप दर्द, गतिविधि की सीमा, विकलांगता और रोगी के जीवन की गुणवत्ता पर प्रभाव पड़ता है।

उद्देश्य : गठिया से पीड़ित रोगियों में सीरम यूरिक एसिड स्तर और जीवन की गुणवत्ता में व्यक्तिगत होम्योपैथिक दवाओं के प्रभावों की जांच करना।

विधि : कोलकाता, होम्योपैथिक मेडिकल कॉलेज एवं हॉस्पिटल, कोलकाता के बाह्य रोगी विभाग में गठिया से पीड़ित 32 व्यस्कों (एसीआर–ईयूलर गाउट वर्गीकरण मानदंडों के अनुसार निदान) पर एक संभावित, एकल हाथ, गैर यादृच्छिक, खुला, अवलोकन परीक्षण किया गया था। सीरम यूरिक एसिड स्तर में परिवर्तन प्राथमिक परिणाम था (बेसलाइन बनाम 3 महीने); गाउट असेसमेंट प्रश्नावली v2.0 (GAQ2; आधारभूत बनाम 3 महीने) और उपाय खुद को मेडिकल आउटकम प्राफाइल v2.0 (MYMOP2; आधारभूत हर महीने, 3 महीने तक) माध्यमिक परिणाम थे। इंटेंशन–टू–ट्रीट सैंपल (दत्र32) का विश्लेषण ैचैप्ठडोअण्20 में किया गया था

परिणाम : रोगियों की औसत आयु 47.6 वर्ष थी; पुरुष व महिला अनुपात 5:3 था। दोनों सीरम यूरिक एसिड स्तर (मिलीग्राम/डीएल) (7.6 ± 1.4 बनाम 6.0 ± 1.5; औसत कमी : 1.6, 95% CI 1.1, 2.1, P<0.001, स्टूडेंट्स टी टेस्ट) और GAQ_2 का कुल स्कोर (45.0 ± 9.1 बनाम 21.0 ± 14.0; औसत कमीः 24.0, 95% CI 19.1, 29.0, *P*<0.001, स्टूडेंट्स *t* टेस्ट) 3 महीनों में काफी कम हो गया। डल्डब्ल्2 स्कोर ने 4 अलग–अलग समय बिंदुओं पर अनुदैर्ध्य रुप से प्राप्त किया, सांख्यिकीय रुप से महत्वपूर्ण कटौती (*P*<0.001, एक तरह से दोहराया एनोवा) का पता चला। अधिकांशतः निर्दिष्टितम दवा बेंजोइकम एसिडम थी।

निष्कर्ष : इस अध्ययन में गठिया के लक्षणों को कम करने और जीवन की गुणवत्ता में सुधार लाने में व्यक्तिगत होम्योपैथिक दवाओं के उपचार के प्रभाव का पता चला।

Un essai d'observation prospectif pour évaluer l'effet des médicaments homéopathiques chez les patients souffrant de goutte

Contexte : La goutte est une arthrite inflammatoire associée à l'hyperuricémie et au dépôt de cristaux d'urate monosodique inter-articulaire (MSU), entraînant de la douleur, une limitation de l'activité, un handicap et ayant un impact sur la qualité de vie du patient. **Objectif :** Examiner les effets des médicaments homéopathiques personnalisés sur le taux d'acide urique sérique et la qualité de vie chez les patients souffrant de goutte. **Méthodes :** Un essai d'observation prospectif ouvert non randomisé sur groupe unique a été mené sur 32 adultes souffrant de goutte (diagnostiqués selon les critères de classification de la goutte ACR-EULAR) au service de consultations externes de l'hôpital 'Calcutta Homoeopathic Medical College and Hospital' à Kolkata. Les changements dans le taux d'acide urique sérique étaient le principal résultat (au départ par rapport à après 3 mois) ; le questionnaire 'Gout Assessment Questionnaire v2.0' (GAQ_2 – Questionnaire d'évaluation de la goutte ; au départ par rapport à après 3 mois) et le 'Measure Yourself Medical Outcome Profile v2.0' (MYMOP2 – Profil après l'auto-évaluation des résultats médicaux) ; au départ, chaque mois, jusqu'à 3 mois) étaient les résultats secondaires. L'échantillon 'intention de traiter' (n = 32) a été analysé dans SPSS®IBM®v.20. **Résultats :** L'âge moyen des patients était de 47,6 ans; le ratio hommes/femmes était de 5:3. Le taux d'acide urique sérique (mg/dl) chez les deux [7,6 ± 1,4 contre 6,0 ± 1,5 ; réduction moyenne 1,6, 95 % CI 1.1, 2,1, *P*<0,001, Test t de Student] et le score GAQ_2 total [45,0 ± 9,1 contre 21,0 ± 14,0 ; réduction moyenne : 24,0, 95 % CI 19,1, 29,0, *P*<0,001, test t de Student] ont baissé de manière sensible sur la période de 3 mois. Les scores MYMOP2 obtenus longitudinalement à 4 moments différents ont également révélé des réductions statistiquement significatives (*P*<0,001, mesure répétée à sens unique ANOVA). Le médicament le plus souvent prescrit était le *Benzoicum acidum*. **Conclusion :** Cette étude a révélé un effet thérapeutique prometteur de médicaments homéopathiques personnalisés pour soulager les symptômes de la goutte et améliorer la qualité de vie.

Ensayo prospectivo observacional para evaluar el efecto de los medicamentos homeopáticos en pacientes con gota

Fundamentos: La gota es una artritis inflamatoria asociada a hiperuricemia y depósito de cristales de urato monosódico (UMS) que da lugar a dolor, limitación de la actividad y discapacidad, además de tener un impacto en la calidad de vida. **Objetivos:** Examinar los efectos de los medicamentos homeopáticos individualizados sobre los niveles de ácido úrico en suero y la calidad de vida de los pacientes que sufren de gota. **Métodos:** Se ha realizado un ensayo prospectivo, de brazo único, no aleatorizado, abierto y observacional en 32 adultos con gota (diagnóstico establecido conforme a los criterios de clasificación ACR-EULAR Gout) en el departamento ambulatorio del *The Calcutta Homoeopathic Medical College and Hospital*, Kolkata, India. El parámetro principal fueron los cambios en los niveles de ácido úrico (inicio frente a 3 meses); mientras que los secundarios fueron el Cuestionario de Evaluación de la Gota v2.0 (GAQ_2; inicio frente a 3 meses) y el perfil *Measure Yourself Medical Outcome Profile* v2.0 (MYMOP2; inicio, cada mes, hasta 3 meses). La muestra de intención de tratamiento (n=32) se analizó en el programa SPSS®IBM®v.20. **Resultados:** La edad media de los pacientes era de 47,6 años, la relación de hombres/mujeres de 5:3. Los niveles séricos de ácido úrico (mg/dl) [7,6 ± 1,4 frente a 6,0 ± 1,5; reducción media: 1,6, IC del 95 % 1,1, 2,1, *P*<0,001, prueba t de Student] y la puntuación total GAQ_2 [45,0 ± 9,1 frente a 21,0 ± 14,0; reducción media: 24,0, IC del 95% 19,1, 29,0, *P*<0,001, prueba t de Student] se fueron reduciendo significativamente a lo largo de 3 meses. Las puntuaciones MYMOP2 obtenidas en 4 diferentes momentos también mostraron reducciones estadísticamente significativas (*P*<0,001, ANOVA unilateral de mediciones repetidas). El medicamento más frecuentemente indicado fue *Benzoicum acidum*. **Conclusiones:** Este estudio mostró un efecto terapéutico prometedor de los medicamentos homeopáticos individualizados en aliviar los síntomas de gota y mejorar la calidad de vida.

Prospektive Beobachtungsstudie Beurteilung der Wirkung homöopathischer Arzneimittel in Gichtpatienten

Hintergrun: Die Gicht ist eine entzündiche Arthritis, die mit Hyperurikämie und Ablagerung intraartikulärer mononatriumurat enthaltende Krystalle einhergeht, und in Schmerzen, Einschränkung der Tätigkeiten, Behinderung und Beeinträchtigung der Lebensqualität entartet. **Zielsetzung:** Untersuchung der Auswirkungen individualisierter homöopathischer Arzneimittel auf den Harnstoffspiegel im Serum und die Lebensqualität der mit Gicht erkrankten Patienten.. **Methode:** Es wurde eine prospektive, einarmige, nicht randomisierte, offene Beobachtungsstudie an 32 erwachsenen Gichtpatienten (Diagnose nach den Klassifikationskriterien der ACR-EULAR Gout) in der Ambulanzabteilung des *Calcutta Homoeopathic Medical College and Hospital, Kolkata*. Die Veränderungen im Harnstoffspiegel im Serum stellen den primären Endpunkt dar (Anfang vs. 3 Monate) dar, während die sekundären Endpunkte in der Beurteilung des *Gout Assessment Questionnaire* v2.0 (GAQ2; Anfang vs. 3 Mante) und der *Measure Yourself Medical Outcome Profile* v2.0 (MYMOP2; Anfang, jeden Monat bis zu 3 Monaten) bestanden. Die *Intention-to-treat* Analyse (n=32 Patienten) wurde mit dem Program SPSS®IBM®v.20 durchgeführt. **Ergebnisse:** Das Durchschnittsalter der Patienten war 47,6 Jahre; das Verhältniss Männer:Frauen war 5:3. Der Harnstoffspiegel im Serum (mg/dl) [7,6 ± 1,4 vs. 6,0 ± 1,5; durchschnittliche Senkung 1,6, 95% CI 1,1, 2,1, *P*<0,001, Student's t Test] und die Gesamtpunktzahl GAQ_2 [45,0 ± 9,1 vs. 21,0 ± 14,0; durchshnittliche Senkung: 24,0, 95% CI 19,1, 29,0, *P*<0;001, Student's t Test] zeigten eine signifikante Senkung während eines Zeitraums von 3 Monaten. Die longitudinal an 4 unterschiedlichen Zeitpunkten erhaltenen MYMOP2-Scores zeigten auch statisch signifikante Senkungen (*P*<0.001, wiederholte einseitige ANOVA). Das am häufigsten angezeigte Arzneimittel war *Benzoicum acidum*. **Fazit:** Diese Studie zeigt eine vielversprechende therapeutische Wirkung seitens individualisierter homöopathischer Arzneimittel in Bezug auf die Erleichterung der Gichtsymptome und die Besserung der Lebensqualität.

前瞻性觀察研究：評估順勢療法療劑對痛風病人的效用

背景：痛風是一種炎症性關節炎，伴有高尿酸血症和關節內尿酸鈉晶體（MSU）沉積，導致疼痛、活動受限、殘疾，影響患者的生活品質。

目的：探討個人化順勢療法藥物對痛風患者血尿酸水平及生活品質的效用。

方法：在加爾各答順勢療劑法醫學院和醫院的門診部，對32位成人痛風患者（根據ACR-EULAR痛風分類標準診斷）進行前瞻性、單組、非隨機、開放性、觀察性試驗。血清尿酸水平的變化是主要結果（基線vs 3個月）；痛風評估問卷v2.0（GAQ2；基線 vs 3個月）和測量自己的醫療結果v2.0（MYMOP2；基線，每月，3個月以上）是次要結果。在 SPSS®IBM®v.20中以治療意向 (ITT) 樣本（n=32）作分析。

結果：患者平均年齡47.6歲，男女比例5:3。血清尿酸水平（mg/dl）[7.6±1.4 vs.6.0±1.5；平均下降1.6,95%CI 1.1,2.1，P<0.001，學生t檢驗] 和GAQ2總分 [45.0±9.1 vs.21.0±14.0；平均下降24.0，95% CI 19.1,29.0，P<0.001，學生t檢驗] 在3個月內顯著下降。在4個不同時間點縱向獲得的MYMOP2得分也顯示出統計學上的顯著降低（P<0.001，單因子獨立變異數分析 ANOVA）。最常指引出的藥物是安息香酸 。

結論：本研究顯示，個人化的順勢療法藥物在舒緩痛風症狀、提高生活品質方面具有良好的治療效果。