Original Article

Symptom prevalence in a cohort of 147 patients improved with the homoeopathic medicine *Ocimum canum*: A multicenter, open, observational, clinical verification study

Rajkumar Manchanda[1], Parthasarathi Chakraborty[2]*, K. C. Das[9], M. K. Rai[3], Ojit Singh[4], P. K. Pradhan[5], Darshan K. Singh[6], Munmun Koley[7], Subhranil Saha[7], Chaturbhuja Nayak[8]

[1]Central Council for Research in Homoeopathy, New Delhi, [2]Dr. Anjali Chatterjee Regional Research Institute (Homoeopathy), Kolkata, West Bengal, [3]Retired, Dr. D.P. Rastogi Central Research Institute (Homoeopathy), Noida, Uttar Pradesh, [4]Regional Research Institute for Homoeopathy, Imphal, Manipur, [5]Regional Research Institute for Homoeopathy, Puri, Odisha, [6]Private practitioner, [7]Independent Researcher, [8]President, Homoeopathy University, Jaipur, Rajasthan, [9]Retired, Dr. Anjali Chatterjee Regional Research Institute (Homoeopathy), Kolkata, West Bengal, India

Abstract

Context: Clinical verification is an ongoing research program of the Council that verified many rare homoeopathic drugs. **Aims:** To clinically verify the "symptomatology" of *Ocimum canum* by ascertaining the prevalence of symptoms. **Materials and Methods:** The study was a multicenter, open, observational trial. A total of 214 patients were enrolled after matching with the available symptom compendium and eligibility criteria in seven units/institutes of the Council. The medicine was prescribed in 6C, 30C, 200C and 1M potencies as per the need of each patient, following homoeopathic principles and protocol developed by the Council. The collected data were presented in terms of descriptive statistics. Prevalence of the symptoms in the responding and nonresponding population was compared using Chi-square or Fisher's exact test. **Results:** A total of 173 complete cases were analyzed; male/female: 76/97; mean age: 31.09 years. There were "clinical successes" in 147 cases (85.0%) and failures in 26 (15.0%), judged subjectively by the physicians. A minimum of two prescriptions was considered for pick-listing each symptom as per protocol. The number of symptoms verified was proving symptoms (n = 10), symptoms from other literature (n = 12), and new observations (n = 42). **Conclusions:** A total of 22 symptoms were verified, and 42 new clinical symptoms were identified. The newly observed general symptoms and polar symptoms may be worth consideration and evaluation. Further replication and estimation of likelihood ratio in general practice settings are crucial for confirmatory inclusion of the symptoms in homoeopathic literature.

Key words: Clinical verification, Homoeopathy, Observational study, *Ocimum canum*

Introduction

More than 50% of all drugs used clinically are the origin of natural products,[1] and medicinal plants are widely used in a drug as a source of natural product.[2] Among these, traditional medicinal plants are used in health problems due to their important therapeutic potentials and comparatively less side effects than conventional drugs. Plants of genus *Ocimum* belong to family Lamiaceae and are collectively called as Basil. They are a diverse and rich source of aromatic essential oils, composed of phenylpropenes, for example, eugenol, methyl eugenol and methyl chavicol. Biological properties of *Ocimum* oils are related to their various interesting applications as antimicrobial, antioxidant, repellent, insecticidal, larvicidal, nematicidal, and therapeutic (anti-inflammatory, antinociceptive, antipyretic, antiemetic, antiulcer, analgesic, antihelminthic, antistress, anticarcinogenic, skin permeation enhancer, immunomodulatory, cardioprotective, antiasthmatic, antidiabetic, anti-lipidemic) agents.[3,4] Two types of flavonoids

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***Address for correspondence:** Dr. Parthasarathi Chakraborty, Dr. Anjali Chatterjee Regional Research Institute (Homoeopathy), Under Central Council for Research in Homoeopathy, 50, Rajendra Chatterjee Road, Kolkata - 700 035, West Bengal, India.
E-mail: drpsch@yahoo.co.in

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are present in *Ocimum* species – lipophilic flavonoid aglycones (external flavonoids)[5,6] and polar flavonoid glycosides (nevadensin, xanthomicrol, salvigenin).[7,8] Other components of therapeutic importance include methyl chavicol, linalool, trans-methyl cinnamate,[9,10] sesquiterpene hydrocarbons (bergamotene and beta-caryophyllene), oct-1-en-3-ol and 3-octanol,[11] heavy metals (copper, zinc, iron, manganese, nickel, and cadmium),[12] and few minerals (calcium, potassium, sodium, phosphorus, and magnesium).[13] *Ocimum canum* is well known due to its use in skin disease, diabetes, cold, fever, dysentery, digestive, stomache, genitourinary problems, headaches, etc.[14] The plant leaves are reported to be rich in volatile essential oils of therapeutic importance;[15] for example, antibacterial (*Staphylococcus aureus*, *Bacillus subtilis*, *Trichophyton mentagrophytes var. interdigitale*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Salmonella typhi*, *B. subtilis*, and *Escherichia coli*);[15-18] fungicidal;[19-23] acaricidal;[24,25] antiglycemic and antiatherogenic;[26-29] antioxidant properties by preventing oxidative stress, hepatic ischemia and providing hepatoprotection;[6,30-36] anti-melanoma and radioprotective activity.[37] It has shown some promising activity in treatment of obesity also.[38] It has been used as an alternative to synthetic insecticides and mosquito repellants[39-41] and even mosquito antifeedant, ovicidal, larvicidal, and nymphicidal potential.[42-46] Some antiplasmodial effects against *Plasmodium falciparum* and mature-stage larvae of *Anopheles funestus* have also been detected.[47,48]

Regulatory standard of this drug has been mentioned as monograph in the 6th volume of Homoeopathic Pharmacopoeia of India, 1974.[49,50] However, the evidence for successful treatment with *Ocimum canum* has remained anecdotal rather than experimental. Some leading Homoeopathic Materia Medicas[51-57] mention and some individual webpages[58-61] claim its therapeutic utility, especially in urolithiasis, haematuria, renal colic accompanied by nausea and vomiting, coryza, spermatorrhoea and uric acid diathesis. The drug was standardized by the Central Council for Research in Homoeopathy (CCRH) at its Institutes/Units in Hyderabad, Ghaziabad, and Lucknow for pharmacognostic, physicochemical, and pharmacological aspects.[62] Later, drug proving was conducted by CCRH in double-blind, randomized, placebo-controlled design in 1996–1998 at Drug Proving Research Unit, Kolkata, and Homoeopathic Drug Research Institute, Lucknow, in 200C, 30C, and 12C potencies on 25 healthy human volunteers.[62,63] Following that, clinical verification was carried out by the CCRH.[62] This paper presents the symptom compendium of *Ocimum canum* verified clinically during the Council's 2nd phase verification studies in 2005–2010.

Materials and Methods

The study was conducted at seven Institutes/Units of CCRH: Central Research Institute, Noida (Uttar Pradesh), Regional Research Institute, Puri (Odisha), Regional Research Institute, Shimla (Himachal Pradesh), Regional Research Institute, Kolkata, (West Bengal), Regional Research Institute, Imphal (Manipur), Clinical Research Unit, Port Blair (Andaman and Nicobar Islands), and Clinical Verification Unit, Vrindaban (Uttar Pradesh).

As per the inclusion criteria, the patients from all age groups, both sexes, having symptomatic similarity with *Ocimum canum*, and persons willing to participate were included in the study. If patient was taking any acute medicine, he/she was included in the study after a washout period of 1 week. Exclusion criteria were patients unwilling to participate, patients having a clinical presentation not corresponding with the study medicine, patients on regular medication for any systemic disease, and patients under chronic medicinal treatment. After providing patient information sheet in local vernaculars, informed written consent was obtained from the eligible subjects or the guardians in case of minors before participating in the study.

The study medicine was procured from one Good Manufacturing Practice compliant homoeopathic pharmacy in various potencies, namely, 6C, 30C, 200C, and 1M, and was distributed to above-mentioned institutes/units. First, the presenting signs and symptoms of the patients were recorded in case recording proforma. After that, the symptoms were repertorized using a repertory prepared for clinical verification by CCRH, and then, a specially developed Materia Medica was consulted for final selection of the remedy. Later, all these works were incorporated in one book published by CCRH.[63] If the presenting symptoms of the patient correspond with *Ocimum canum*, then the medicine was prescribed in 6C potency thrice a day till the improvement or aggravation occurred or for 5–7 days allowing the medicine to act. The medicine was dispensed by corresponding institute/unit pharmacy. In follow-up visits, the changes in signs and symptoms were noted. If there was any sign of improvement, then placebo was prescribed. If there was status quo, next higher potencies were prescribed in ascending order, 30C twice a day for 3–5 days in acute cases or for 5–7 days in chronic cases; 200C once a week were prescribed and were observed for 2 weeks. 1M potencies were advised once a fortnight, followed by 2 weeks observation. Keeping in mind the wide variation of presenting diseases or complaints, the timeline for follow-up was defined as 2 weeks or oftener *a priori* in the protocol. However, as each symptom has its own timeframe for recovery, provision had been kept to adjust the schedule as per individual's need and appropriateness of the cases. Dosage was decided as per the need of the case and in accordance with homoeopathic principles. Any potency could be tried for twice only. If adequate responses were not elicited, the cases were restudied and switched over to the next potency. If no change was observed even after the change of potencies also, then the case was closed and considered as a clinical failure or status quo. If the patient presented with new symptoms of mild intensity, placebo was prescribed; while the appearance of severe symptoms (new or aggravation of existing symptoms)

with sufficient strength to cause considerable discomfort to the patient, called for a change of medicine or therapy and this case was considered as deteriorated one. "Clinical success" was defined *a priori* as cases showing clinical improvement, objective or subjective, of present complaint(s) as judged by the investigating physician(s) and/or as reported by the patient(s). "Clinical failures" were such cases showing "status quo" and/or worsening or deterioration of the condition, or cases requiring change of medicines. All the data were collected and compiled in specially designed Excel spreadsheet for analysis. Data were presented using descriptive statistics – mean, standard deviations (SDs), absolute values, percentages, and 95% confidence intervals (CIs). As per protocol, a minimum of two prescriptions for each symptom have been considered for pick-listing. Prevalence of the symptoms in the responding and nonresponding population was compared using Chi-square or Fisher's exact test, keeping $P < 0.05$ two-tailed as statistically significant.

Results

A total of 214 patients were enrolled having similar "symptomatology" of *Ocimum canum* and meeting the prespecified eligibility criteria. Of these, 41 dropped out and 173 results per protocol were analyzed at the end of the study [Figure 1]. Dropped out patients, as and when reported, were treated in the general out-patients of respective institutes/units.

The mean age of the patients was 31.09 years (SD = 16.98); 97 (56.1%) were female. The sociodemographic features are further detailed in Table 1. There were clinical successes in 147 cases (85.0%) and failures in 26 (15.0%) cases, judged subjectively by the physicians. The clinically verified symptoms were enlisted along with the outcomes on the basis of existing proving records and the symptoms available in other literature and also the new clinically observed symptoms or traits, those are not mentioned elsewhere [Table 2]. Among the 147 patients responding well to *Ocimum canum*, a total of 18 different types of clinical conditions or diagnoses were obtained; respiratory tract infection was the most frequent ($n = 83$; 56.46%) [Table 3].

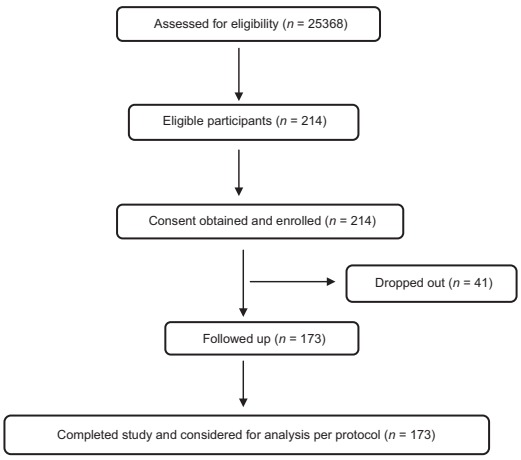

Figure 1: The study flow diagram

Among the proving symptoms and clinical verification symptoms of CCRH, the following were most frequently observed symptoms:

- "Dry cough; agg. morning, evening; amel. warm drinks, tea" ($n = 54$; prevalence 36.7% in the responding group, 95% CI: 29.1, 45.1)
- "Sneezing with watery discharge; agg. cold; amel. warm drinks, tea" ($n = 50$; prevalence 34.0% in the responding group, 95% CI: 26.5, 42.3)
- "Sore throat, itching, difficult deglutition; agg. cold; amel. warm drinks, tea" ($n = 34$; prevalence 23.1% in the responding group, 95% CI: 16.8, 30.9)
- "Headache with heaviness in forehead; agg. morning, bending forward; amel. lying down" ($n = 24$; prevalence 16.3% in the responding group, 95% CI: 10.9, 23.5).

Table 1: Sociodemographic features of the patients

Features	*n* (%)	95% CI
Gender (*n*=173)		
Male	76 (43.9)	36.5-51.7
Female	97 (56.1)	48.3-63.5
Age (years; *n*=173)¥	31.09 (17.0)	−2.2-64.4
Age (groups) (*n*=173)		
≤18	41 (23.7)	17.7-30.9
19-30	59 (34.1)	27.2-41.7
31-50	50 (28.9)	22.4-36.4
51-70	18 (10.4)	6.5-16.2
≥71	5 (2.9)	1.1-7.0
Religion (*n*=135)		
Hindu	128 (94.8)	89.2-97.7
Islam	5 (3.7)	1.4-8.9
Christian	2 (1.5)	0.3-5.8
Marital status (*n*=124)		
Married	72 (58.1)	48.9-66.8
Unmarried	52 (41.9)	33.3-51.1
Occupation (*n*=122)		
Homemaker	47 (38.5)	30.0-47.8
Student	43 (35.3)	27.0-44.5
Service	19 (15.6)	9.9-23.5
Business	9 (7.4)	3.6-13.9
Clinical observations		
Height (cm; *n*=130)¥	153.52 (16.0)	122.1-184.9
Weight (kg; *n*=131)¥	50.09 (11.6)	27.4-72.8
BMI (*n*=202)¥	21.31 (4.2)	13.1-29.5
BMI classes (*n*=130)		
Underweight (<18.5)	33 (25.4)	18.3-33.9
Normal (18.5-24.9)	75 (57.7)	48.7-66.2
Overweight (25-29.9)	19 (14.6)	9.3-22.1
Obese I and Obese II	3 (2.3)	0.6-7.1
SBP (mmHg; *n*=121)¥	119.63 (9.6)	100.8-138.5
DBP (mmHg; *n*=121)¥	78.20 (6.5)	65.4-91.0
Pulse rate (/min; *n*=129)¥	75.32 (4.6)	66.4-84.3
Respiratory rate (/min; *n*=130)¥	17.98 (1.6)	14.9-21.1
Temperature (°C; *n*=100)¥	36.64 (0.5)	35.7-37.6

¥Continuous data presented as mean (SD). SD: Standard deviation; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; BMI: Body mass index; CI: Confidence interval

Table 2: List of verified symptoms of the homoeopathic medicine *Ocimum canum* (*n*=173)

	Symptom prevalence (%) in medicine population (*n*=173)	95% CI	Symptom prevalence (%) in responding population (*n*=147)	95% CI	Symptom prevalence (%) in not responding population (*n*=26)	95% CI	Chi square value at df=1 (Yates corrected)	*P*
Symptoms (CCRH proving)[63]								
Headache, throbbing, right sided, aggravation. morning, amelioration after sleep	4 (2.3)	0.7-6.2	4 (2.7)	0.8-7.3	0	0-16.0	0.0	1.000
Headache with heaviness in forehead; agg. morning, bending forward; amel. lying down	24 (13.9)	9.3-20.1	24 (16.3)	10.9-23.5	0	0-16.0	3.7	0.027*
Heaviness in head; agg. standing; amel. rest	5 (2.9)	1.1-7.0	5 (3.4)	1.3-8.2	0	0-16.0	0.1	1.000
Sneezing with watery discharge; agg. cold; amel. warm drinks, tea	54 (31.2)	24.5-38.8	50 (34.0)	26.5-42.3	4 (15.4)	5.0-35.7	2.8	0.096
Sore throat, itching, difficult deglutition; agg. cold; amel. warm drinks, tea	39 (22.5)	16.7-29.6	34 (23.1)	16.8-30.9	5 (19.2)	7.3-40.0	0.4	0.533
Dry cough; agg. morning, evening; amel. warm drinks, tea	60 (34.7)	27.7-42.3	54 (36.7)	29.1-45.1	6 (23.1)	9.8-44.1	1.3	0.260
Cough with yellowish expectoration	9 (5.2)	2.6-10.0	9 (6.1)	3.0-11.7	0	0-16.0	0.7	0.358
Ankle swollen, painful, especially left	12 (6.9)	3.8-12.1	7 (4.8)	2.1-9.9	5 (19.2)	7.3-40.0	5.1	0.020*
Itching eruptions on face, forehead, elbow, forearm, from knees to legs; scratching, followed by burning	5 (2.9)	1.1-7.0	4 (2.7)	0.9-7.3	1 (3.9)	0.2-21.6	0.1	0.562
Itching eruption over whole body; agg. night, warmth of bed, heat; amel. scratching, cold application	12 (6.9)	3.8-12.1	11 (7.5)	4.0-13.3	1 (3.9)	0.2-21.6	0.1	0.696
Symptoms from other literature[52-58]								
Vertigo on rising and sitting down	3 (1.7)	0.5-5.4	3 (2.0)	0.5-6.3	0	0-16.0	0.0	1.000
Nasal congestion	5 (2.9)	1.1-7.0	4 (2.7)	0.9-7.3	1 (3.9)	0.2-21.6	0.1	0.562
Toothache, especially right sided; amel. pressing the teeth together	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0-16.0	0.2	1.000
Noise heard painfully in the ears	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0-16.0	0.2	1.000
Menses late, scanty or profuse	3 (1.7)	0.5-5.4	2 (1.4)	0.2-5.3	1 (3.9)	0.2-21.6	0.0	0.388
Whitish-yellow leukorrhea	5 (2.9)	1.1-7.0	5 (3.4)	1.3-8.2	0	0-16.0	0.1	1.000
Renal colic, especially right sided	10 (5.8)	3.0-10.7	5 (3.4)	1.3-8.2	5 (19.2)	7.3-40.0	7.5	0.008*
Ureteric colic, sore pain	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0-16.0	0.2	1.000
Burning pain in urethra during urination; urine profuse, burning	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0-16.0	0.2	1.000
Burning during micturition	5 (2.9)	1.1-7.0	2 (1.4)	0.2-5.3	3 (11.5)	3.03–31.3	4.9	0.025*
Renal colic, cramps, hematuria, with nausea and vomiting	4 (2.3)	0.7-6.2	3 (2.0)	0.5-6.3	1 (3.9)	0.2–21.6	0.0	0.482
Scanty urine	3 (1.7)	0.5-5.4	0	0-3.2	3 (11.5)	3.03–31.3	11.2	0.003*

Contd...

Table 2: Contd...

	Symptom prevalence (%) in medicine population (*n*=173)	95% CI	Symptom prevalence (%) in responding population (*n*=147)	95% CI	Symptom prevalence (%) in not responding population (*n*=26)	95% CI	Chi square value at df=1 (Yates corrected)	*P*
New clinical observations								
Thermal relations								
Ambithermal	35 (20.2)	14.7-27.2	30 (20.4)	14.4-28.0	5 (19.2)	7.3–40.0	0.0	0.899
Chilly	59 (34.1)	27.2-41.7	50 (34.0)	26.5-42.3	9 (34.6)	18.0–55.6	0.0	0.869
Hot	28 (16.2)	11.2-22.7	27 (18.4)	12.7-25.8	1 (3.9)	0.2–21.6	2.5	0.082
Desire for								
Chilly, spicy	5 (2.9)	1.1-7.0	4 (2.7)	0.9-7.3	1 (3.9)	0.2–21.6	0.1	0.562
Cold food, cold drink, ice cream	28 (16.2)	11.2-22.7	25 (17.0)	11.5-24.3	3 (11.5)	3.0–31.3	0.2	0.772
Salty	34 (19.7)	14.2-26.5	27 (18.4)	12.7-25.8	7 (26.9)	12.4–48.1	0.6	0.457
Non-veg	4 (2.3)	0.7-6.2	4 (2.7)	0.9-7.3	0	0–16.0	0.0	1.000
Sour	3 (1.7)	0.5-5.4	2 (1.4)	0.2-5.3	1 (3.9)	0.2–21.6	0.0	0.388
Sweet	39 (22.5)	16.7-29.6	39 (26.5)	19.8-34.6	0	0–16.0	7.5	0.006*
Aversion to								
Brinjal	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0–16.0	0.2	1.000
Oily rich food	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0–16.0	0.2	1.000
Potato	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0–16.0	0.2	1.000
Salty	5 (2.9)	1.1-7.0	5 (3.4)	1.3-8.2	0	0–16.0	0.1	1.000
Sour	5 (2.9)	1.1-7.0	5 (3.4)	1.3-8.2	0	0–16.0	0.1	1.000
Sweet	2 (1.2)	0.2-4.6	1 (0.7)	0.0-4.3	1 (3.9)	0.2–21.6	0.2	0.279
Appetite								
Decreased	27 (15.6)	10.7-22.1	21 (14.3)	9.3-21.2	6 (23.1)	9.8–44.1	0.7	0.251
Increased	20 (11.6)	7.4-17.5	19 (12.9)	8.2-19.7	1 (3.9)	0.2–21.6	1.0	0.316
Thirst								
Decreased	8 (4.6)	2.2-9.2	8 (5.4)	2.6-10.8	0	0–16.0	0.5	0.608
Increased	7 (4.1)	1.8-8.5	7 (4.8)	2.1-9.9	0	0–16.0	0.4	0.596
Tongue								
Clean	135 (78.0)	71.0-83.8	111 (75.5)	67.6-82.1	24 (92.3)	73.4–98.7	2.7	0.099
Coated (white, yellow)	33 (19.1)	13.7-25.9	32 (21.8)	15.6-29.5	1 (3.9)	0.2–21.6	3.5	0.031*
Moist	31 (17.9)	12.7-24.6	28 (19.1)	13.2-26.5	3 (11.5)	3.0–31.3	0.4	0.578
Dry	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0–16.0	0.2	1.000
Taste								
Bitter	3 (1.7)	0.5-5.4	3 (2.0)	0.5-6.3	0	0–16.0	0.0	1.000
Stool								
Dry, hard, constipated	36 (20.8)	15.2-27.8	35 (23.8)	17.4-31.7	1 (3.9)	0.2–21.6	4.2	0.040*
Scanty, unsatisfactory	6 (3.5)	1.4-7.7	5 (3.4)	1.3-8.2	1 (3.9)	0.2–21.6	0.2	1.000
Urine								
Offensive	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0–16.0	0.2	1.000
Perspiration								
Profuse	27 (15.6)	10.7-22.1	27 (18.4)	12.7-25.8	0	0–16.0	4.4	0.016*
Scanty	3 (1.7)	0.5-5.4	3 (2.0)	0.5-6.3	0	0–16.0	0.0	1.000
Sleep								
Disturbed	3 (1.7)	0.5-5.4	2 (1.4)	0.2-5.3	1 (3.9)	0.2–21.6	0.0	0.388
Mind								
Anxious	3 (1.7)	0.5-5.4	2 (1.4)	0.2-5.3	1 (3.9)	0.2–21.6	0.0	0.388
Confused	5 (2.9)	1.1-7.0	4 (2.7)	0.9-7.3	1 (3.9)	0.2–21.6	0.1	0.562
Desire company	15 (8.7)	5.1-14.2	15 (10.2)	6.0-16.6	0	0–16.0	1.8	0.131
Desire to be alone	4 (2.3)	0.7-6.2	3 (2.0)	0.5-6.3	1 (3.9)	0.2–21.6	0.0	0.482
Intelligent	25 (14.5)	9.7-20.8	24 (16.3)	10.9-23.5	1 (3.9)	0.2–21.6	1.9	0.131
Mild, gentle	12 (6.9)	3.8-12.1	12 (8.2)	4.5-14.1	0	0–16.0	1.2	0.217

Contd...

Table 2: Contd...

	Symptom prevalence (%) in medicine population (*n*=173)	95% CI	Symptom prevalence (%) in responding population (*n*=147)	95% CI	Symptom prevalence (%) in not responding population (*n*=26)	95% CI	Chi square value at df=1 (Yates corrected)	*P*
Concentration difficult	2 (1.2)	0.2-4.6	2 (1.4)	0.2-5.3	0	0–16.0	0.2	1.000
Forgetful, weak memory	27 (15.6)	10.7-22.1	22 (15.0)	9.8-22.0	5 (19.2)	7.3–40.0	0.1	0.564
Dull	4 (2.3)	0.7-6.2	4 (2.7)	0.9-7.3	0	0–16.0	0.0	1.000
Sad, gloomy, melancholic	3 (1.7)	0.5-5.4	2 (1.4)	0.2-5.3	1 (3.9)	0.2–21.6	0.0	0.388
Irritable	6 (3.5)	1.4-7.7	5 (3.4)	1.3-8.2	1 (3.9)	0.2–21.6	0.2	1.000
Malaise, lethargic	2 (1.2)	0.2-4.6	2 (1.3)	0.2-5.3	0	0–16.0	0.2	1.000

CI: Confidence interval; CCRH: Central Council for Research in Homoeopathy; Chi-square or Fisher exact test applied; *P<0.05 two-tailed considered as statistically significant

Among the existing symptoms available from other literature, the most frequently observed symptom was "renal colic, especially right sided" (n = 5, prevalence 3.4% in the responding group, 95% CI: 1.3, 8.2). Symptom "scanty urine" did not show any improvement (n = 0, prevalence 0% in the responding group, 95% CI: 0, 3.2) [Table 2].

Among new clinical symptoms, the most frequently observed symptoms were as follows:

- "Tongue clean" (n = 111, prevalence 75.5% in the responding group, 95% CI: 67.6, 82.1)
- "Thermal relation – chilly" (n = 50, prevalence 34.0% in the responding group, 95% CI: 26.5, 42.3)
- "Desire for sweet" (n = 39, prevalence 26.5% in the responding group, 95% CI: 19.8, 34.6)
- "Stool dry, hard, constipated" (n = 35, prevalence 23.8% in the responding group, 95% CI: 17.4, 31.7)
- "Thermal relation – ambithermal" (n = 30, prevalence 20.4% in the responding group, 95% CI: 14.4, 28.0)
- "Desire for salty food" (n = 34, prevalence 18.4% in the responding group, 95% CI: 12.7, 25.9)
- "Tongue coated (white, yellow)" (n = 32, prevalence 21.8% in the responding group, 95% CI: 15.6, 29.5)
- "Tongue moist" (n = 28, prevalence 19.1% in the responding group, 95% CI: 13.2, 26.5)
- "Thermal relation – hot" (n = 27, prevalence 18.4% in the responding group, 95% CI: 12.7, 25.8)
- "Desire for cold food, cold drink, ice cream" (n = 25, prevalence 17.0% in the responding group, 95% CI: 11.5, 24.3)
- "Appetite decreased" (n = 21, prevalence 14.3% in the responding group, 95% CI: 9.3, 21.2)
- "Perspiration profuse" (n = 27, prevalence 18.4% in the responding group, 95% CI: 12.7, 25.8)
- "Forgetful, weak memory" (n = 22, prevalence 15.0% in the responding group, 95% CI: 9.8, 22.0)
- "Mild, gentle" (n = 12, prevalence 8.2% in the responding group, 95% CI: 4.5, 14.1)
- "Appetite increased" (n = 19, prevalence 12.9% in the responding group, 95% CI: 8.2, 19.7).

Significantly, higher prevalence of the symptoms under question in the responding population than in the nonresponding population was found in case of 5 symptoms:

1. Headache with heaviness in forehead; agg. morning, bending forward; amel. lying down (24/147 vs. 0/26; Chi-square [Yates corrected] =3.7; P = 0.027 two-tailed)
2. Desire for sweet (39/147 vs. 0/26; Chi-square [Yates corrected] =7.5; P = 0.006 two-tailed)
3. Tongue coated white or yellow (32/147 vs. 1/26; Chi-square [Yates corrected] =3.5; P = 0.031 two-tailed)
4. Stool dry, hard, constipated (35/147 vs. 1/26; Chi-square [Yates corrected] =4.2; P = 0.040 two-tailed)
5. Perspiration profuse (27/147 vs. 0/26; Chi-square [Yates corrected] =4.4; P = 0.016 two-tailed)

However, as far as the peculiarity of the symptoms is considered, the first three may be segregated further and may be deemed as the most promising symptoms for future research [Table 4].

Discussion

A total of 22 symptoms of *Ocimum canum* were verified, of which 10 symptoms were from the compendium of proving, carried out previously by the Council and the rest 12 were clinical re-confirmation of symptoms from other literature. Besides, 42 new clinical symptoms were also identified. Most frequently encountered clinical conditions were respiratory tract infections, migraine, arthritis, renal stone, ureteric stone, and dermatitis.

At this point of time, likelihood ratios (LRs) seems to be the mainstay of future homoeopathic research for confirming the accuracy of the symptoms enlisted under any drug (i.e., drug and Materia Medica validation).[64,65] Retrospective assessment of prevalence and LR of symptoms in good responders could be a mean for better selection of symptoms for prospective research; however, feasibility of conducting such retrospective investigations deserves further discussion. Although the presence and/or absence of *Ocimum canum* symptoms in the "medicine worked" population can be

Table 3: Most frequent clinical diagnoses among the population responding well to *Ocimum canum* (*n*=147)

Diagnoses	*n* (%)	95% CI
RTI	83 (56.5)	48.0-64.5
Migraine	26 (17.7)	12.1-25.0
Arthritis	13 (8.8)	5.0-14.9
Renal stone, ureteric stone	12 (8.2)	4.5-14.1
Dermatitis	11 (7.5)	4.0-13.3
Earache	5 (3.4)	1.3-8.2
Leucorrhoea	4 (2.7)	0.9-7.3
UTI	3 (2.0)	0.5-6.3

RTI: Respiratory tract infection (both upper and lower); UTI: Urinary tract infection; CI: Confidence interval

Table 4: Promising symptoms for future research

Headache with heaviness in forehead; aggravation morning, bending forward; amelioration lying down
Desire for sweet
Tongue coated white or yellow

identified in retrospective way, still finding out the same in the remainder of the population treated during the period of study from the available CCRH database is not feasible. Hence, formation of the 2 × 2 contingency table of prognostic research and calculation of LR does not appear to be probable at this point of time. These symptoms with low prevalence need greater number of cases to establish substantial LR. All these results should be considered as provisory and need confirmation through prospective research of real prevalence in order to the knowledge of medicines and more importantly, to increase posterior chance of correct selection of medicine, improve prescription accuracy and clinical outcomes.[66] The causal association can be tested prospectively and systematically in all cases using modified Naranjo's criteria[67] in future studies.

The spheres of action of medicine identified were head, nose, respiratory tract, ear, genitourinary system, musculoskeletal system, and skin. A few mental symptoms were elicited – anxious; confused; desires company; desire to be alone; intelligent; mild, gentle; concentration difficult; forgetful, weak memory; dull; sad, gloomy, melancholic; irritable; malaise, lethargy. Moreover, our initial observation also elicited a few polar symptoms – both thermally chilly and hot; desire for and aversion to salty food, sour, and sweet; appetite increased and decreased; thirst increased and decreased; tongue clean and coated; tongue moist and dry; sweat scanty and profuse; desire company and desire to be alone; intelligent and dull. These opposite (polar) symptoms warrant further rigorous evaluation.[68] Apart from the above observations, during the study, a group of valuable symptoms also emerged reflecting the general characters of the drug and thereby widening the probable scope of its therapeutic applicability. The mental features obtained were sad, depressed, melancholic mood; forgetful and weak memory; irritability; and aversion to noise, light, and crowd. These may be considered as useful clinical concomitants, carrying much importance to prescribe the medicine. The overall results generated were contributed by different study sites, indicating enhanced generalizability of the study findings. However, being an observational trial, this study cannot address the threats to various internal validity issues; for example, absence of matching, randomization and blinding, the placebo effect, the therapeutic relationship with the clinician (empathy, compassion, social desirability, etc.), the regression effect toward the mean, and the use of undisclosed concomitant treatments, if any. The research protocol should have anticipated and kept provision to address the issues related to spontaneous recovery of the symptoms under question, for example, using modified Naranjo's criteria. However, this observational trial, being exploratory in nature, cannot evaluate the same. In addition, we compared between responding and nonresponding patients for one medicine. This way, we can only get some idea of symptoms that can be further investigated. These could be of great value when compared with similar data of other medicines. However, the prevalence of symptoms should preferably be compared with the whole population. If possible, this can be derived from literature or estimated.[66,69] This symptom prevalence should necessarily be higher in the responding population than in the whole population to be considered as an indication for the given medicine. However, it depends on the cutoff value for this symptom, which can vary strongly. The prevalence of any symptom under investigation can probably be best assessed in multicenter drug validation or clinical verification programs that can produce more reliable and generalizable nation-wide data. Some data are already available,[66,69] but still in a nascent state and how far they can be extrapolated to the remaining nations remains a matter subjected to future research.

Conclusions

This paper generated a list of clinically verified symptoms of *Ocimum canum* and warrants further evaluation using enhanced methodological rigor. On many occasions, a limited number of prescriptions were generated for specific symptoms making interpretation difficult. Calculation of LR will enable more accurate and quantitative description of strength of the probable or claimed characteristic symptoms of the drug, based on empirical evidence instead of assumption. Hence, further confirmation of the symptoms in larger sample size, analysis of polarity, and prospective estimation of LR of the symptoms using Bayesian statistical methods in routine practice is necessary before inclusion of the symptoms in Homoeopathic Materia Medica and Repertory.

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Conflicts of Interest

There are no conflicts of interest.

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Symptomenhäufigkeit in einer Kohorte von 147 Patienten, gebessert durch das homöopathischen Mittel *Ocimum canum*: eine offene, empirische Multi-Center-Studie klinischer Verifikationen

ZUSAMMENFASSUNG

Hintergrund: Klinische Verifikationen gehören zu den laufenden Forschungsprojekten des „Council for Research in Homeopathy“, bei dem viele seltene homöopathische Arzneimittel verifiziert werden.

Ziel: Die klinische Verifikation der Symptomatologie von *Ocimum canum* durch Feststellung der Symptomenhäufigkeit.

Material und Methode: Es handelt sich hierbei um einen offene, empirische Multi-Center-Studie. Sie wurde an insgesamt 214 Patienten durchgeführt, wobei die vorliegenden Arzneisymptome und die Auswahlkriterien an sieben Abteilungen/Instituten des „Central Council for Research in Homeopathy“ zur Übereinstimmung gebracht werden. Die Arznei wurde in C6, C30, C200 und 1M je nach den Bedürfnissen des Patienten, gemäß homöopathischer Grundprinzipien und dem vom „Council of Research“ entworfenen Protokoll verabreicht. Die gesammelten Daten wurden in einer deskriptiven Statistik vorgestellt. Die Verteilung der reagierenden und nicht-reagierenden Population wurde mit entsprechendem Chi-Quadrat-Test oder dem exakten Fischer-Test durchgeführt.

Ergebnisse: Insgesamt wurden 173 vollständige Fälle analysiert; männlich/weiblich: 76/97; Durchschnittsalter: 31,09 Jahre. Klinische Erfolge wurden von Ärzten in 147 Fällen (85,0%) und Fehlschläge in 26 Fällen (15,0%) subjektiv beurteilt. Als Faustregel wurden mindestens zwei Verordnungen pro Symptom für die Auswahlliste herangezogen. Die Anzahl der verifizierten Symptome ergab sich folgendermaßen: Prüfungssymptome (n=10), Symptome aus anderen Literaturquellen (n=12), neue klinische Beobachtungen (n=42).

Fazit: Insgesamt wurden 22 Symptome verifiziert und 42 neue klinische Symptome beobachtet. Die neu beobachteten Allgemein- und Polaritätssymptome sollten weiter berücksichtigt und ausgewertet werden. Weitere Replikation und Schätzung von Wahrscheinlichkeit im allgemeinen praktischen Rahmen sind entscheidend für die Aufnahme der Symptome in die Literatur.

Prevalencia de síntomas en una cohorte de 147 pacientes que mejoraron con el medicamento homeopático *Ocimum canum*: Estudio clínico, observacional, multicéntrico, abierto de verificación

RESUMEN

Contexto: La verificación clínica es un programa de investigación en curso del *Council*, en el que se han comprobado muchos medicamentos homeopáticos raros.

Objetivos: Verificar clínicamente la “sintomatología” de *Ocimum canum* y establecer la prevalencia de los síntomas.

Materiales y métodos: Se trataba de un estudio clínico, observacional, multicéntrico abierto. Se incluyó un total de 214 pacientes después comprobar la coincidencia de los síntomas disponibles, el compendio del medicamento y los criterios de elegibilidad de siete unidades/institutos del *Council*. El medicamento se prescribió en las potencias de 6C, 30C, 200C y 1M, en función de las necesidades de cada paciente, cumpliendo con los principios homeopáticos y el protocolo desarrollado por el *Council*. Los datos recogidos se presentaron con estadísticas descriptivas. La prevalencia de los síntomas en la población de respondedores y no respondedores se comparó con la prueba de chi cuadrado o la prueba exacta de Fisher.

Resultados: Se analizó un total de 173 casos completos; la proporción de hombres / mujeres era de 76/79 y la edad media se situó en 31,09 años. Conforme a la valoración subjetiva de los médicos, se dieron 147 (85,0%) casos de “éxito clínico” y 26 (15,0%) “fracasos”. Como regla general, se consideró un mínimo de dos prescripciones para el listado de cada síntoma. El número de síntomas verificados fue el siguiente: síntomas de patogenesias (n = 10), síntomas de otras bibliografías (n = 12) y observaciones clínicas nuevas (n = 42).

Conclusiones: Se verificó un total de 22 síntomas y se identificaron 42 síntomas clínicos nuevos. Hay que tener en cuenta y evaluar los síntomas generales nuevos observados y los síntomas polares. Es esencial replicar estos estudios y estimar la relación de probabilidad en la práctica clínica general para la confirmación de los síntomas y su incorporación en la bibliografía homeopática.

147 रोगियों के समूह में लक्षण प्रसार में होम्योपैथी दवा ओसिमम केनम द्वारा इलाज सुधार : बहुकेंद्रिक, मुक्त विश्लेषणात्मक, नैदानिक सत्यापन का अध्ययन।

सार

संदर्भः नैदानिक सत्यापन परिषद् के निरंतर चलने वाले अनुसंधान कार्यक्रम हैं जो कई दुर्लभ होम्योपैथिक औषधियाँ सत्यापित करते हैं।

उद्देश्यः लक्षणों की संभाव्यता की खोज के माध्यम से ओसिमम केनम के नैदानिक 'लक्षणों' को नैदानिक रुप से सत्यापित करना।

सामग्री और पद्धतिः यह अध्ययन बहुकेंद्रिक, मुक्त विश्लेषणात्मक परीक्षण के तौर पर किया गया। उपलब्ध संग्रहीत लक्षणों और परिषद् के सात इकाइयों/संस्थानों में पात्रता मानदंड के साथ मिलान करने के उपरांत कुल 214 रोगियों का पंजीकरण किया गया। प्रत्येक रोगी की आवश्यकता के अनुसार होम्योपैथी सिद्धांतों और परिषद् द्वारा विकसित प्रोटोकॉल के अनुसार 6सी, 30सी, 200सी और 1 एम पोटेंसी (मात्रा) में औषधि दी गयी। एकत्र किए गए आंकड़े विवरणात्मक सांख्यिकी के रूप में प्रस्तुत किए गए। औषधि अनुकूल और प्रतिकूल जनसंख्या में इन लक्षणों की व्यापकता की तुलना ची–वर्ग या फिशर सटीक परीक्षण का उपयोग करते हुए की गयी।

परिणामः कुल 173 मामलों का विश्लेषण किया गया पुरुष/महिला अनुपात 76:97 व औसतन उम्र 31.09 साल। 147 (85.0 प्रतिशत) के मामलों में 'नैदानिक सफलता' मिली और 26 (15.0 प्रतिशत) में असफलता चिकित्सकों द्वारा आत्मगत रूप से आंकलन किया गया। प्रत्येक लक्षण के निर्धारण के लिए न्यूनतम दो नुस्खों पर विचार किया गया। सत्यापित लक्षणों की संख्या इस प्रकार हैः प्रमाणित लक्षण (एन = 10), अन्य शास्त्र समूहों से लक्षण (एन = 12), और नए नैदानिक विश्लेषण (एन = 42)।

निष्कर्षः कुल 22 लक्षणों का सत्यापन किया गया और 42 नए नैदानिक लक्षणों का पता लगाया गया। विश्लेषण किए गए नवीन सामान्य लक्षण और पोलर लक्षण विचारणीय और मूल्यांकन के योग्य है। इसके अलावा होम्योपैथी साहित्य में लक्षणों की पुष्टि को शामिल करने के लिए सामान्य अभ्यास व्यवस्था में प्रतिकृति और संभाव्य अनुपात का अनुमान महत्व रखता है।