

Symptom prevalence in a cohort of 65 patients improved with the homoeopathic medicine *Mangifera indica*: A multicentric open observational clinical verification study

Raj K. Manchanda¹, Partha Sarathi Chakraborty^{2*}, Pramodji Singh³, M. K. Rai⁴, Ojit Singh⁵, D. K. Singh⁶, Souradipta Paul⁷, Chaturbhuj Nayak⁸

¹Central Council for Research in Homoeopathy, New Delhi, ²Dr. Anjali Chatterjee Regional Research Institute Homoeopathy, Kolkata, West Bengal,

³Clinical Verification Unit (Homoeopathy), Vrindaban, Uttar Pradesh, ⁴Retired, Dr. D. P. Rastogi Central Research Institute (Homoeopathy), Noida, Uttar Pradesh,

⁵Regional Research Institute (Homoeopathy), Imphal, Manipur, ⁶Retired, Homoeopathic Drug Research Institute, Lucknow, Uttar Pradesh, ⁷Independent Researcher,

⁸President, Homoeopathy University, Jaipur, Rajasthan, India

Abstract

Introduction: Clinical verification is an ongoing research program of the Council that verified many rare homoeopathic drugs. **Aim:** To clinically verify the 'symptomatology' of *Mangifera indica* by ascertaining the symptoms improved during verification. **Materials and Methods:** The study was a multicentric open label observational trial. Total 114 patients were enrolled after matching with the available symptom compendium and eligibility criteria in five centres of the Council. The medicine was prescribed in 6C, 30C, 200C and 1M potencies, as per need of the patient following the homoeopathic principles and protocol developed by the Council. The collected data were presented in terms of descriptive statistics. Prevalence of symptoms in the responding and non-responding population has been compared using Chi-square test. **Results:** Among the total 114 patients enrolled in the study, 77 patients who completed the follow up were analysed, as there were 37 drop out cases. The demographic analysis shows, male/female: 41/36, mean age 28.61 years. There was "clinical success" in 65 cases (84.41%) and failures in 12 cases (15.59%), judged subjectively by the physicians. A minimum of two prescriptions were considered for pick listing each symptom as a rule of thumb. **Conclusions:** Total 16 CCRH proving symptoms were verified, 4 symptoms from other literatures were also verified. 51 new clinical symptoms/symptom components were identified. Further replication and estimation of likelihood ratio in general practice setting is crucial for confirmation and inclusion of such symptoms in homoeopathic literatures.

Keywords: Cohort, Clinical verification, Homoeopathy, *Mangifera indica*, Observational study

INTRODUCTION

Traditional medicinal plants are used in different health problems due to their important therapeutic potentials and comparatively less side effects than the conventional drugs. *Mangifera indica*, also known as mango, aam, is an important herb in indigenous medical systems for over 4000 years.^[1]

Mangifera indica L. is an evergreen tree in the anacardiaceae family that grows to a height of 10-45 metres, dome shaped with dense foliage, typically heavy branched from a stout trunk. It is native tropical Asia and has been cultivated in the Indian subcontinent for over 4000 years and is now found naturalized in most tropical countries.^[1]

The bark of the tree is used for the homoeopathic preparation of *Mangifera indica*.^[2]

The chromatography and mass spectrometry study reveals that the bark contains many important constituents, viz., protocatechic acid, catechin, mangiferin, alanine etc. which exhibited anti-inflammatory, antioxidative, biosynthesis of proteins, antihelminthic, and other pharmacological properties.^[3-5]

In a folkloric use in Cuba it is reported that the aqueous extract of the bark of the plant is recommended as antispasmodic, antipyretic and as an anti-inflammatory agent. The bark extract (Vimang®)

***Address for correspondence:** Dr. Partha Sarathi Chakraborty, Dr. Anjali Chatterjee Regional Research Institute for Homoeopathy, Kolkata, West Bengal, India. E-mail: drpsch@yahoo.co.in

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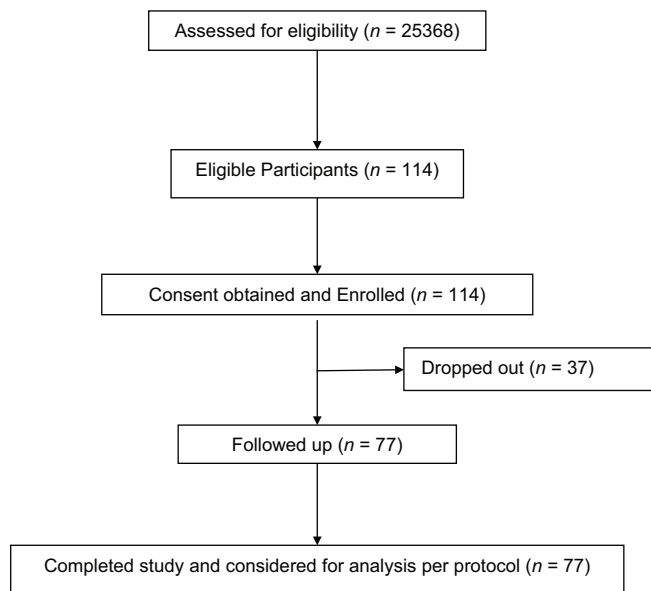


Figure 1: The study flow diagram

was found to be useful as supplement in treatment of various pathologies such as gastric and dermatological disorders, AIDS, cancer and asthma, after conducting both *in vitro* and *in vivo* studies in experimental models.^[6-12]

Another *in vitro* study conducted on Herpes simplex virus with mangiferin showed that it has the capacity to inhibit the replication of HSV-1 and HSV-2 viruses within the cells and even to antagonize the cytopathic effects of HIV.^[13-15] Many other *in-vitro* studies conducted in various cancer cell lines exhibited its anticancerous activity in inhibiting the proliferation and inducing apoptosis of cancer cell lines, suggesting the potentiality of mangiferin as a chemo preventive agent.^[16-19] The stem bark extract of MI has also found to possess antiplasmodial and antipyretic activity.^[20,21]

The regulatory standard of this drug has been mentioned as monograph in the 7th volume of Homoeopathic Pharmacopoeia of India (HPI), 1999. The proving of the drug *Mangifera indica* Linn, was conducted by the CCRH in 1995–1996 using double blind method. The drug was proved in 6CH and 30CH potencies in ascending order. The proving was carried out at (i) Regional Research Institute, New Delhi, (ii) Drug Proving Research Unit, Ghaziabad (Uttar Pradesh). Seventeen (17) provers in the age group of 18–49 years had taken part in the proving including three females.^[22] This paper presents the symptom compendium of *Mangifera indica* Linn verified clinically under the councils Clinical Verification Programme.

MATERIALS AND METHODS

The study was conducted between 2005–2010 in 5 centres of CCRH: Homoeopathic Drug Research Institute, Lucknow; Regional Research Institute(H), Shimla; Regional Research Institute(H), Imphal; Dr. D. P. Rastogi Central Research Institute(H), Noida and Clinical Verification Unit(H), Vrindaban.

As per the inclusion criteria, the patients from all age groups, both sexes, having symptomatic similarity with *Mangifera indica*, 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 wash-out period of one week. Patients unwilling to participate, having a clinical presentation not corresponding with the study medicine, patients on regular medication for any systemic diseases and patients under chronic medicinal treatment were excluded from the study.

The study medicine was procured from a Good Manufacturing Practice (GMP) compliant homoeopathic pharmacy of India in various potencies, viz. 6C, 30C, 200C and 1M and was distributed to above mentioned institutes/units. After recording the presenting signs and symptoms of the patients in case recording proforma, 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. If the presenting symptoms of the case corresponded with the symptomatology of *Mangifera indica*, then the medicine was prescribed in 6C potency and was repeated three times a day, till improvement/aggravation occurred when the drug was stopped; otherwise it was continued for 5/7 days allowing the drug to act. Then the subsequent potencies like 30C, 200C, 1M were prescribed following the guidelines defined in the protocol. In cases of improvement under action of any of the above mentioned potencies, Placebo was prescribed so far the improvement continued. If the improvement stopped, i.e., if the case relapsed or became standstill, then the prescription was repeated in same potency. In no case the same potency was repeated for more than two times. In cases where aggravation of the presenting symptoms resulted under trial without any relief, then change of medicine was considered. When new symptoms appeared after administration of the medicine, and if these new symptoms were mild and did not cause much concern to the patient, placebo was prescribed for one week. But if no improvement followed or worsening occurred after one week, then change of medicine was considered. If the new symptoms were severe and cause considerable discomfort to the patient from the beginning, then change of medicine/therapy was considered at once.

In cases where no perceptible improvement occurred after adequate repetition of medicine in different potencies, then it was searched for any obstacle(s) to cure and steps were taken to remove it (when identified) as far as possible. In cases where no response was achieved even after removal of probable obstacle(s), the case was referred for appropriate medical care.

The cases were followed up and assessed once a week or even earlier, if required.

Each and every case has been evaluated in depth to find out any known causative factors to find out the etiological factors and also any obstacle to recovery whether present or not which may hinder the action of the drug and once found, efforts were made to remove/minimize them. A nutritious, well balanced, healthy diet was recommended, as it can help in balancing of immune system.

'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 no change and/or worsening or deterioration of the condition, or cases requiring change of medicines/therapy. All the data were collected and compiled in specially designed excel spreadsheet for analysis. Data were presented using descriptive statistics – mean, standard deviations (SD), absolute values, percentages and 95% confidence intervals (CI). As a rule of thumb, a minimum of two prescriptions for each symptom have been considered for pick-listing. Prevalence of the symptoms in the responding and non-responding population was compared using Chi Square test, keeping *P* value less than 0.05 (two tailed) as statistically significant.

RESULTS

A total of 114 patients were enrolled in the study having similar 'symptomatology' of *Mangifera indica*, and meeting the pre-specified eligibility criteria. Of these, 37 cases were dropped out and 77 complete cases were analysed [Figure 1]. The socio demographic information of these patients is given in Table 1. Clinical success and failure was judged subjectively by the treating physicians. "Clinical success" in 65 cases (84.41%), and "Clinical failure" was observed in 12 cases (15.59%).

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. Among the completed cases, 41 cases (53.25%) were male, 36 cases (46.75%) were females. The mean age of the patients was 28.61 years (SD = 19.05). The patients enrolled were from all age groups but majority were from 16-30 years ($n = 31$, 40.26%). 74 patients (96.10%) were Hindu, 42 were single (54.55%) and 26 patients (33.77%) were married. No. of student patients were more than of other category ($n = 30$, 38.96%) [Table 5]. The mean height and weight of the patients were 145.09 cm ($n = 64$; SD = 26.08) and 48.01 kg ($n = 65$; SD = 14.02) respectively. The mean SBP and DBP were 118.06 ($n = 62$, SD = 11.51) and 75.89 ($n = 62$, SD = 6.42) respectively [Table 6]. Majority of patients have had normal BMI ($n = 35$, 54.69%) [Table 7]. Among the 65 cases who responded well to *Mangifera indica*, a total of 10 clinical conditions or diagnosis were obtained; with "Acute upper respiratory tract infection" being the commonest ($n = 20$, 30.77%) [Table 8].

Among the proving symptoms of CCRH, the followings were most frequently observing symptoms with prevalence rate higher in responding population than in the non-responding population.

1. Coryza with watery nasal discharge (prevalence in responding population: $n = 35$ (53.85%); 95% CI = 0.42, 0.65)
2. Coryza with heaviness of head (prevalence in responding population: $n = 11$ (16.92%); 95% CI = 0.09, 0.28)
3. Appetite diminished (prevalence in responding population: $n = 11$ (16.92%); 95% CI = 0.09, 0.28)

4. Pain in joints, better from pressure (prevalence in responding population: $n = 5$ (7.69%); 95% CI = 0.03, 0.17)
5. Fever with chill and body-ache (prevalence in responding population: $n = 5$ (7.69%); 95% CI = 0.03, 0.17).

Among the existing symptoms from other literatures, the most frequently observed symptom were:

1. Skin of face dark as if sunburn and swollen (Prevalence in responding population: $n = 16$ (24.7); 95% CI = 0.16-0.36)
2. White spots on skin (Prevalence in responding population: $n = 2$ (3.1%); 95% CI = 0.008-0.1)

But the prevalence of these symptom were found higher in non responding population [$n = 5$ (41.7%), 95% CI = 0.19-0.68 & $n = 2$ (16.7), 95% CI = 0.05-0.45]

Among the new clinical symptoms observed during verification, the most frequently observed symptoms with prevalence rate higher in responding population than in the non-responding population were:

1. Dry cough, *agg.* at night (prevalence in responding population: $n = 4$ (6.15%); 95% CI = 0.02, 0.15)
2. Pain in throat while talking (prevalence in responding population: $n = 3$ (4.62%); 95% CI = 0.01, 0.13).

During Clinical verification of *Mangifera indica*, it has been observed that patients with some distinct character have responded well to the prescribed drug. These distinct features though have not been modified under the action of the drug in trial (hence cannot be classified under Clinical Symptoms) in the present study, but may come out as important personal characteristics in future studies. These distinct features are given below along with their prevalence in responding population which have been found higher than the non-responding population.

1. Desire for Salty food (prevalence in responding population: $n = 15$ (23.08%); 95% CI = 0.14, 0.34)
2. Thermal reaction - Chilly (prevalence in responding population: $n = 22$ (33.85%); 95% CI = 0.24, 0.46)
3. Thermal reaction - Ambithermal (prevalence in responding population: $n = 23$ (35.38%); 95% CI = 0.25, 0.48)
4. Tongue-clean & moist (prevalence in responding population: $n = 51$ (78.46%); 95% CI = 0.67, 0.87)
5. Memory weak, forgetfulness (prevalence in responding population: $n = 9$ (13.85%); 95% CI = 0.07, 0.24).

There were altogether 57 symptoms, where the prevalence rate in responding population was found higher than the prevalence rate in non-responding population. But the prevalence of these symptoms in the responding population was not found to be statistically significant ($P > 0.05$).

DISCUSSION

A total of 71 symptoms were verified which includes CCRH proving symptoms, symptoms from other existing literatures and symptoms identified as new clinical symptoms. Among these 71 symptoms, 54 symptoms were identified where

the symptom prevalence was higher in the responding population than the symptom prevalence in non-responding population. But the prevalence of none of these symptoms was found statistically significant. 16 symptoms were verified from CCRH proving symptoms of *Mangifera indica*; 10 new symptom components of the proving symptoms were also identified and are presented in italics under the respective proving symptoms [Table 1]. Only 4 symptoms were verified from other existing homoeopathic literature [Table 2]. During the study, 41 entire new symptoms (Clinical symptoms) were identified [Table 3]. Some distinct clinical patterns/features were also identified during the study among the responding population due to their higher prevalence [Table 4]; though these features were not modified under the action of the drug and hence cannot be classed with Clinical symptoms, but they may come out as important personal characteristics in future studies when their prevalence in general population and Likelihood ratio will be estimated.

The “Acute upper respiratory tract infection” was found to be the most commonly responded clinical condition followed by “Vitiligo”.

At this point of time, Bayesian probability and likelihood ratios (LR) seem to be the mainstay of future homoeopathic research for confirming/validating the accuracy of the symptoms listed under any drug.^[23,24] Retrospective assessment of prevalence and LR of symptoms in good responders could be a mean for better selection of symptoms for prospective research; but feasibility of conducting such retrospective analysis deserves further discussion. Though the prevalence of symptoms of *Mangifera indica*, can be identified in the good response group of study population through retrospective analysis of available case records, but finding out the prevalence of these symptoms in remainder of the general population treated during the study period in those institutes/units of CCRH where the study had been conducted, is not feasible. Hence, formulation of

Table 1: List of verified symptoms (Central Council for Research in Homoeopathy proving) of *Mangifera indica*

CCRH proving symptoms ^[22]	Symptom prevalence (%) in medicine population (n=77)	95% CI	Symptom prevalence (%) in responding population (n=65)	95% CI	Symptom prevalence (%) in not responding population (n=12)	95% CI	χ^2 at df=1 (yates corrected)	P
Head								
Headache	5 (6.49)	0.03-0.14	4 (6.15)	0.02-0.15	1 (8.33)	0.01-0.35	0	1
<i>On vertex < at noon > from pressure</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
<i>< after 10 am > from pressure</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
<i>> from pressure</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Nose								
Coryza with thin watery nasal discharge	39 (50.65)	0.40-0.62	35 (53.85)	0.42-0.65	4 (33.33)	0.14-0.61	0.983	0.321
<i>< in morning and in evening</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
With heaviness in head	13 (16.88)	0.10-0.27	11 (16.92)	0.09-0.28	2 (16.67)	0.05-0.45	0	1
<i>With body ache</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
<i>With cough and scanty expectoration < at night</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
<i>With stuffiness of nose < in open air</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
<i>With burning in nose > in open air</i>	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Mouth								
Painful ulceration on lip	4 (5.19)	0.02-0.13	4 (6.15)	0.02-0.15	0	0-0.24	0.031	0.86
Teeth								
Pain in teeth	7 (9.09)	0.04-0.18	6 (9.23)	0.04-0.19	1 (8.33)	0.01-0.35	0	1
<i>< while brushing and on chewing</i>	4 (5.19)	0.02-0.13	3 (4.62)	0.01-0.13	1 (8.33)	0.01-0.35	0	1

Contd...

Table 1: Contd...

CCRH proving symptoms ^[22]	Symptom prevalence (%) in medicine population (n=77)	95% CI	Symptom prevalence (%) in responding population (n=65)	95% CI	Symptom prevalence (%) in not responding population (n=12)	95% CI	χ^2 at df=1 (yates corrected)	P
< from warmth	3 (3.90)	0.01-0.10	3 (4.62)	0.01-0.13	0	0-0.24	0	1
Grinding of teeth during sleep at night	3 (3.90)	0.01-0.10	3 (4.62)	0.01-0.13	0	0-0.24	0	1
Stomach								
Appetite diminished	12 (15.58)	0.09-0.29	11 (16.92)	0.09-0.28	1 (8.33)	0.01-0.35	0.103	0.748
Stool								
Stool loose, watery, offensive	2 (2.60)	0.007-0.09	2 (3.08)	0.008-0.10	0	0-0.24	0	1
Sleep								
Disturbed sleep without dreams	3 (3.90)	0.01-0.10	2 (3.08)	0.008-0.10	1 (8.33)	0.01-0.35	0.003	0.956
Un-refreshing sleep	2 (2.60)	0.007-0.09	2 (3.08)	0.008-0.10	0	0-0.24	0	1
Extremities								
Pain in joints	6 (7.79)	0.04-0.16	6 (9.23)	0.04-0.19	0	0-0.24	0.26	0.61
> from pressure	5 (6.49)	0.03-0.04	5 (7.69)	0.03-0.17	0	0-0.24	0.127	0.721
< from exertion	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Pain with weakness in extremities, especially in legs < from exertion> from pressure	3 (3.90)	0.01-0.10	1 (1.54)	0.002-0.08	2 (16.67)	0.05-0.45	2.81	0.094
Fever								
Fever with chill and body ache	5 (6.49)	0.03-0.04	5 (7.69)	0.03-0.17	0	0-0.24	0.127	0.722
Generalities								
Body ache	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1

CCRH: Central Council for Research in Homoeopathy; CI: Confidence interval

Table 2: List of verified symptoms (from other literatures - Boericke Materia Medica and Lotus Materia Medica) of *Mangifera indica*

Symptoms for other literature	Symptom prevalence (%) in medicine population (n=77)	95% CI	Symptom prevalence (%) in responding population (n=65)	95% CI	Symptom prevalence (%) in not responding population (n=12)	95% CI	χ^2 at df=1 (yates corrected)	P
Throat								
Tonsillitis								
With sore throat, painful, < cold drinks	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Extremities								
Vericose veins on right leg with stiffness and heaviness in leg < from exertion	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Skin								
Skin of face dark as if sun burn and swollen	21 (27.27)	0.19-0.38	16 (24.62)	0.16-0.36	5 (41.67)	0.19-0.68	0.75	0.387
White spots	4 (5.19)	0.02-0.13	2 (3.08)	0.008-0.10	2 (16.67)	0.05-0.45	1.54	0.215
With itching	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Itching on palms	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1

CI: Confidence interval

Table 3: List of new clinical symptoms of *Mangifera indica*

Clinical symptoms	Symptom prevalence (%) in medicine population (n=77)	95% CI	Symptom prevalence (%) in responding population (n=65)	95% CI	Symptom prevalence (%) in not responding population (n=12)	95% CI	χ^2 at df=1 (yates corrected)	P
Head								
Heaviness of head	3 (3.90)	0.01-0.11	2 (3.08)	0.008-0.11	1 (8.33)	0.01-0.35	0.003	0.958
With giddiness	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
> from pressure	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Premature graying of hair-in occipital region	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Mouth								
Increased salivation and lassitude	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Teeth								
Grinding of teeth during sleep at night	3 (3.90)	0.01-0.10	3 (4.62)	0.01-0.13	0	0-0.24	0	1
Throat								
Pain in throat	7 (9.09)	0.04-0.18	7 (10.77)	0.05-0.20	0	0-0.24	0.417	0.518
While talking	3 (3.90)	0.01-0.10	3 (4.62)	0.01-0.13	0	0-0.24	0	1
With rawness of throat	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
With soreness in throat < on swallowing	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
With hardness of hearing and of ringing in ear	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
With choking sensation in throat	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Voice hoarse, choked	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Stomach								
Heartburn	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Abdomen								
Flatulence with heaviness in abdomen	2 (2.60)	0.007-0.09	1 (1.54)	0.002-0.08	1 (8.33)	0.01-0.35	0.138	0.71
Stool								
Constipation	6 (7.79)	0.04-0.16	4 (6.15)	0.02-0.15	2 (16.67)	0.05-0.45	0.438	0.508
With unsatisfactory stool	5 (6.49)	0.03-0.14	3 (4.62)	0.1-0.13	2 (16.67)	0.05-0.45	0.845	0.358
With frequent desire	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Stool hard, irregular	3 (3.90)	0.01-0.10	2 (3.08)	0.008-0.10	1 (8.33)	0.01-0.35	0.003	0.958
Desire to pass stool while taking meal	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Diarrhoea < after eating	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Urine								
Frequent pale yellow urine < at night	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Frequent desire for urination	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Burning and scanty urine < from hot drinks	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Respiration								
Dry cough	7 (9.09)	0.04-0.18	7 (10.77)	0.05-0.20	0	0-0.24	0.417	0.518
< in morning	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
< at night	4 (5.19)	0.02-0.13	4 (6.15)	0.02-0.15	0	0-0.24	0.031	0.86
< from cold drinks	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
With hoarseness of voice	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Asthmatic	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Back								
Backache	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Male								
Seminal emission (nightly)	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34

Contd...

Table 3: Contd...

Clinical symptoms	Symptom prevalence (%) in medicine population (n=77)	95% CI	Symptom prevalence (%) in responding population (n=65)	95% CI	Symptom prevalence (%) in not responding population (n=12)	95% CI	χ^2 at df=1 (yates corrected)	P
Extremities								
Pain in knee joints	6 (7.79)	0.04-0.16	3 (4.62)	0.01-0.13	3 (25)	0.09-0.53	3.365	0.067
> from pressure	6 (7.79)	0.04-0.16	3 (4.62)	0.01-0.13	3 (25)	0.09-0.53	3.365	0.067
< from walking, from movement	2 (2.60)	0.007-0.09	1 (1.54)	0.002-0.08	1 (8.33)	0.01-0.35	0.138	0.71
< on rising from sitting position	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Skin								
Red papular eruptions with itching on whole body, face and on thighs < at night and from change of weather	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
White spots on different parts of body	21 (27.27)	0.19-0.38	16 (24.62)	0.16-0.36	5 (41.67)	0.19-0.68	0.75	0.387
On upper eye lid	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
On face and on chest	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
On face	7 (9.09)	0.04-0.18	4 (6.15)	0.02-0.15	3 (25)	0.09-0.53	2.372	0.124
With itching	2 (2.60)	0.007-0.09	1 (1.54)	0.002-0.08	1 (8.33)	0.01-0.35	0.138	0.71
Without itching	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
On scalp with itching	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
On upper part of chest	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
On left side of abdomen with itching	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
On middle of thighs	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Red rashes under prepuce with itching and pain < during and after micturation	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Fungal like eruptions over the prepuce not clear out after rubbing and scratching	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Eruptions-reddish, blister like, on face with itching > from scratching, followed by burning and bleeding	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
The back of lobules of ears becomes red with itching < under the sun	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Skin of left cheek is dark and looks like scalded	1 (1.30)	0.002-0.07	0	0-0.06	1 (8.33)	0.01-0.35	0.912	0.34
Red papular eruption on forehead	1 (1.30)	0.002-0.07	1 (1.54)	0.002-0.08	0	0-0.24	0	1
Generalities								
Hypersensitive to cold and dampness	4 (5.19)	0.02-0.13	0	0-0.06	4 (33.33)	0.14-0.61	16.587	0

CI: Confidence interval

2 × 2 contingency table for calculation of LR does not seem possible at this point of time. All these results should be considered as provisory and need confirmation through prospective research. The causal association can be tested prospectively and systematically in all cases using modified Naranjo criteria^[25] in future studies.

The overall results generated were contributed by different study sites/units of the Council, indicating enhanced generalizability of the study findings. However, being an observational trial, this study cannot address the threats to

various internal validity issues, e. g., absence of matching, randomization and blinding, the placebo effect, spontaneous recovery of symptoms under question, the therapeutic relationship with the clinician (empathy, compassion, social desirability, etc.), the regression effect toward the mean, and use of undisclosed adjuvant treatments, if any.

In this study, we compared responding and not-responding 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

Table 4: List of new clinical patterns/features (other than clinical symptoms) identified on the basis of their prevalence in the responding population

Prevalent clinical features	Symptom prevalence (%) in medicine populationn (n=77)	95% CI	Symptom prevalence (%) in responding population (n=65)	95% CI	Symptom prevalence (%) in not responding population (n=12)	95% CI	χ^2 at df=1 (yates corrected)	P
Desire								
Desire for sweet	18 (23.38)	0.1533-0.3127	13 (20)	0.1208-0.3127	5 (41.67)	0.1933-0.6805	1.583	0.208
Desire for salty	16 (20.78)	0.1322-0.3122	15 (23.08)	0.1451-0.3464	1 (8.33)	0.0149-0.3539	0.592	0.442
Tongue								
Clean and moist	60 (77.92)	0.6746-0.8573	51 (78.46)	0.6703-0.8671	9 (75)	0.4677-0.9111	0	1
Coated tongue	9 (11.69)	0.0627-0.8573	7 (10.77)	0.0532-0.2060	2 (16.67)	0.0470-0.4480	0.009	0.924
Mental								
Irritable	10 (12.99)	0.0721-0.2228	7 (10.77)	0.0532-0.2062	3 (25)	0.0889-0.5323	0.774	0.379
Forgetfulness	10 (12.99)	0.0721-0.2228	9 (13.85)	0.0746-0.2427	1 (8.33)	0.0149-0.3539	0.003	0.956
Thermal relation								
Ambithermal	21 (27.27)	0.1858-0.3812	18 (27.69)	0.1829-0.3958	3 (25)	0.0889-0.5323	0	1
Hot	13 (16.88)	0.1014-0.2677	9 (13.85)	0.0746-0.2427	4 (33.33)	0.1381-0.6094	1.528	0.216
Chilly	26 (33.77)	0.2420-0.4488	22 (33.85)	0.2553-0.4596	4 (33.33)	0.1381-0.6094	0	1
Sensitive to both	5 (6.49)	0.0289-0.1671	5 (7.69)	0.0333-0.1678	0	0-0.2425	0.127	0.722

CI: Confidence interval

Table 5: Sociodemographic features of the study population

Features	Prevalence	95% CI
Gender (n=77)		
Male	41 (53.25)	0.42-0.64
Female	36 (46.75)	0.36-0.57
Age (groups) (n=77)		
≤18	30 (38.96)	0.29-0.50
19-30	20 (25.97)	0.17-0.37
31-50	19 (24.68)	0.16-0.35
51-70	5 (6.49)	0.28-0.14
≥71	3 (3.90)	0.01-0.10
Religion (n=77)		
Hindu	74 (96.10)	0.89-0.99
Islam	2 (2.60)	0.007-0.89
Christian	1 (1.30)	0.002-0.07
Marital status (n=68)		
Married	26 (38.24)	0.28-0.50
Unmarried	42 (61.76)	0.49-0.72
Occupation (n=55)		
Housewife	12 (21.82)	0.13-0.34
Student	30 (54.55)	0.42-0.67
Service	5 (9.09)	0.04-0.20
Business	8 (14.55)	0.08-0.26

CI: Confidence interval

of other medicines. However, the prevalence of symptoms should preferably be compared with the whole population. If

possible, this can be estimated or derived from literature.^[26] The 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. The prevalence of any symptom under investigation can probably be best assessed in multi-center drug validation or clinical verification programs that can produce more reliable and generalizable nation-wide data. Some data are already available^[26] 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 study exhibited a list of clinically verified symptoms of *Mangifera indica* and warrants further evaluation using enhanced methodological rigor. On many occasions, 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. So, 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 prior to inclusion of the symptoms in Homoeopathic Materia Medica and Repertory.

Table 6: Observations on clinical parameters

Clinical parameters	Mean	SD
Height (cm; n=64)	147.33	18.96
Weight (kg; n=65)	48.02	14.02
BMI (n=64)	21.84	4.93
SBP (mmHg; n=62)	118.06	11.51
DBP (mmHg; n=62)	75.89	6.42
Pulse rate (/min; n=69)	76.17	6.52
Respiratory rate (/min; n=64)	17.73	1.34
Temperature (°C; n=66)	36.70	0.59

BMI: Body mass index; DBP: Diastolic blood pressure; SBP: Systolic blood pressure; SD: Standard deviation

Table 7: Body mass index classes (n=64)

BMI classes	Prevalence	95% CI
Underweight (BMI: <18.5)	17 (26.56)	0.17-0.38
Normal (BMI: 18.5-24.9)	35 (54.69)	0.43-0.66
Overweight (BMI: 25-29.9)	8 (12.5)	0.06-0.23
Obesity (BMI: >30)	4 (6.25)	0.02-0.15

BMI: Body mass index; CI: Confidence interval

Table 8: Frequently responded clinical conditions (n=65)

Clinical diagnosis/condition	Prevalence	95% CI
AURTI	20 (30.77)	0.21-0.43
Vitiligo	9 (13.85)	0.07-0.24
Stomatitis	4 (6.15)	0.02-0.15

CI: Confidence interval; AURTI: Acute upper respiratory tract infection

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Conflicts of interest

None declared.

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65 रोगियों के समूह में लक्षण की प्रबलता में होम्योपैथिक दवा द्वारा सुधार मैन्जीफेरा इंडिका: एक बहुकेन्द्रीय मुक्त अवलोकनीय नैदानिक सत्यापन अध्ययन सार:

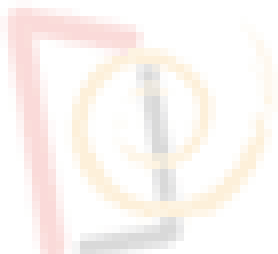
संदर्भ: नैदानिक सत्यापन परिषद् का एक अनुसंधान कार्यक्रम है जिसमें कई दुर्लभ होम्योपैथिक औषधियाँ सत्यापित हुई हैं।

उद्देश्य: मैन्जीफेरा इंडिका से लाभान्वित रोगियों में उपस्थित लक्षणों की जाँच कर इन लक्षणों की प्रबलता का नैदानिक आंकलन।

सामग्री और विधियाँ: अध्ययन एक बहुकेन्द्रीय अनावृत, अवलोकनीय परीक्षण था। परिषद् की पाँच केन्द्रों में उपलब्ध लक्षण संग्रह और पात्रता मापदंड से मिलान के बाद कुल 114 रोगियों को नामांकित किया गया। परिषद् द्वारा विकसित होम्योपैथिक सिद्धांत और प्रोटोकॉल का अनुगमन कर रोगी की आवश्यकता के अनुसार, 6सी, 30सी, 200सी और 1एम पोटेंसी की दवा निर्धारित की गई। एकत्र डेटा वर्णनात्मक सांख्यिकी के रूप में प्रस्तुत किया गया। प्रतिक्रियात्मक और गैर प्रतिक्रियात्मक जनसंख्या में लक्षणों की प्रबलता की ची-स्कॉवर परीक्षण द्वारा तुलना की गई।

परिणाम: अध्ययन में नामांकित कुल 114 रोगियों में से, जिन 77 रोगियों ने अनुवर्तन काल की अवधि को पूर्ण किया उनका विश्लेषण किया गया क्योंकि 37 रोगियों ने अध्ययन छोड़ दिया। जनसांख्यिकी विश्लेषण में पता चला, पुरुष/स्त्री: 41/36, औसत उम्र 28.6 वर्ष थी। 65 मामलों (84.4 प्रतिशत) में नैदानिक सफलता मिली थी और 12 मामलों (15.6 प्रतिशत) में असफलता मिली थी जिसका चिकित्सक द्वारा व्यक्तिगत रूप से निर्णय लिया गया। अनुभव सिद्ध नियम के रूप में प्रत्येक लक्षण सूचीबद्ध कर कम से कम दो मामलों पर चयन के लिए विचार किया गया।

निष्कर्ष: केन्द्रीय होम्योपैथी अनुसंधान परिषद् (सीसीआरएच) के प्रकाशित सिद्ध रिकार्ड से कुल 16 लक्षणों की पहचान की गई, अन्य शास्त्रों से भी 4 लक्षण जांचे गए। 51 नए नैदानिक लक्षण/लक्षणों के घटक पहचाने गए। ऐसे लक्षणों का होम्योपैथिक साहित्य में समावेशन और पुष्टिकरण के लिए सामान्य अभ्यास की परिस्थिति में संभावना अनुपात का अनुमान और भविष्य में पुनरावृत्ति महत्वपूर्ण है।



Symptom-Prävalenz in einer Kohorte von 65 Patienten, gebessert durch die homöopathische Arznei *Mangifera indica*: eine multizentrische klinische Überprüfungsstudie

Abstrakt

Kontext: Klinische Verifikationen sind ein laufendes Forschungsprojektpjekt des “Central of Research in Homeopathy” (CCRH), wodurch viele seltene homöopathische Arzneien verifiziert wurden.

Ziele: Klinische Beurteilung der Häufigkeit der Symptome bei Patienten mit guter Reaktion auf *Mangifera indica* durch die Feststellung der Symptome bei Patienten mit gutem Reaktionsvermögen.

Material und Methoden: Die Studie wurde als eine multizentrische, offene Beobachtung-sstudie angelegt. Insgesamt wurden 114 Patienten nach dem Matching mit dem verfügbaren Symptomkompendium und den Förderkriterien des “Central Council of Re-search in Homeopathy” in sechs (5) zentren eingeteilt. Die Arznei wurde in C 6-, C 30 -, C 200- und 1 M verschrieben, je nach Umständen des Patienten, gemäß den Prinzipien der Homöopathie und dem vom “Central Council of Research in Homeopathy” entwickelten Protokoll. Die gesammelten Daten wurden in Form deskriptiver Statistiken dargestellt. Die Prävalenz der Symptome in der reagierenden und nicht reagierenden Population wurde mit dem Chi-Quadrat-Test verglichen.

Ergebnisse: Unter den insgesamt 114 Patienten, die an der Studie teilgenommen haben, wurden 77 komplette Fälle analysiert, da es 37 Drop-Out-Fälle gab. Die demographisch Analyse zeigt: männlich/weiblich: 41/36; mittleres Alter 28,6 Jahre. Es gab "klinischen Erfolg" in 65 Fällen (84,4%) und Fehlschläge in 12 Fällen (15,6%) aufgrund subjektiver Einschätzung der Ärzte. Es wurden mindestens zwei Verordnungen für die Auswahl jedes Symptoms als Faustregel betrachtet.

Fazit: Insgesamt wurden 16 Symptome aus den veröffentlichten Prüfungsberichten des “Central Council of Research in Homeopathy” verifiziert sowie vier Symptome aus anderen Literaturquellen. 51 neue klinische Symptome/Symptomenelemente wurden erhoben. Eine weitere Replikation und Schätzung der Wahrscheinlichkeitsverhältnisse unter Bedingungen einer Allgemeinenpraxis ist entscheidend für die Bestätigung und Aufnahme dieser Symptome in die homöopathische Literatur.

Prevalencia de síntomas en una cohorte de 65 pacientes que mejoraron con el medicamento homeopático *Mangifera indica*: estudio observacional abierto multicéntrico de verificación clínica.

Resumen

Objetivo: A verificar clínicamente la ‘síntomatología’ de *Mangifera indica* mediante la determinación de los síntomas mejoraron durante la verificación.

Materiales y métodos: Se efectuó un ensayo observacional abierto multicéntrico. En cinco(5) centros del CCRH, se reclutó un total de 114 pacientes que coincidían con el compendio de síntomas disponibles y cumplían los criterios de elegibilidad. El medicamento se prescribió en las potencias 6C, 30C, 200C y 1M, según las necesidades del paciente, aplicando los principios homeopáticos y el protocolo desarrollado por el Council. Los datos recogidos se sometieron a estadísticas descriptivas. Se realizó una comparación de la prevalencia de los síntomas en la población con y sin respuesta aplicando la prueba de chi cuadrado.

Resultados: Del total de los 114 pacientes incluidos en el estudio, se analizaron 77 casos completos y se produjeron 37 retiradas. El análisis demográfico muestra una relación de varones/mujeres de 41/36 con una edad media de 28,6 años. Según la valoración subjetiva de los médicos, se obtuvo un “éxito clínico” en 65 casos (84,4%) y se produjeron 12 fracasos (15,6%). Como regla general, se consideró un mínimo de dos prescripciones para el seleccionar cada síntoma.

Conclusiones: Se identificó un total de 16 síntomas del registro publicado de patogenesias del CCRH; asimismo, se verificaron 4 síntomas de otras bibliografías y 51 síntomas clínicos / componentes sintomáticos nuevos. Para la confirmación e inclusión de estos síntomas en las bibliografías homeopáticas es crucial una posterior replicación y la estimación de la relación de probabilidad en el contexto clínico general.



La prévalence des symptômes chez une cohorte de 65 patients s'est améliorée avec le médicament homéopathique *Mangifera indica*: une étude multicentrique ouverte de vérification clinique sur la base d'observations.

Résumé

Objectif: Vérifier cliniquement la ‘symptomatologie’ de *Mangifera indica* en déterminant l’amélioration des symptômes lors de la vérification.

Matériels et Méthodes: L'étude consistait en un essai multicentrique ouvert à base d'observation. Un total de 114 patients ont été inscrits après correspondance faite avec le recueil des symptômes et les critères d'éligibilité disponibles dans five centres du Conseil. Le médicament a été prescrit dans des potences de 6C, 30C, 200C et 1M, selon le besoin du patient conformément aux principes homéopathiques et au protocole établi par le Conseil. Les données recueillies ont été présentées en termes de statistique descriptive. La prévalence des symptômes chez la population répondante et non-répondante a été comparée à l'aide du test X².

Résultats: Parmi le total de 114 patients inscrits à l'étude, 77 cas complets ont été analysés, car il y avait 37 cas d'abandon. L'analyse démographique montre que le ratio homme-femme était de 41:36, et l'âge moyen de 28,61 ans. Il y a eu un "succès clinique" dans 65 cas (84,41%) et des échecs dans 12 cas (15,59%), jugés subjectivement par les médecins. Un minimum de deux ordonnances ont été prises en compte pour établir la liste de sélection de chaque symptôme en règle générale.

Conclusions: Un total de 16 symptômes probants du CCRH ont été vérifiés, 4 symptômes provenant d'autres publications ont également été vérifiés. 51 nouveaux symptômes cliniques/ composants de symptôme ont été identifiés. Davantage de réplique et d'estimation du rapport de vraisemblance dans le cadre de la pratique générale sont essentielles pour la confirmation et l'inclusion de tels symptômes dans les publications homéopathiques.

標題：65個病人隊列中使用順勢療法藥物芒果後得到改善的症狀普及性：多中心非盲觀察性臨床認證研究。

摘要

背景：臨床認證是委員會一項持續進行的研究計劃，用以查證眾多罕見的順勢療法藥物。

目的：通過臨床評估對芒果有良好反應的病人之症狀普及性，用以確定對該療劑反應良好的病人會展現出的症狀。

材料及方法：該研究是多中心、非盲、觀察性試驗。在評議會中五個中心配對可用症狀編匯以及委員會的納入資格的準則之後，總共114名病人加入研究。依從由評議會製定出來的順勢療法原則和程序，按照病人的個別需要處方出6C、30C、200C和1M層級。收集得來的數據以描述性統計數據呈現。透過卡方測定 (chi-square test) 比較有反應和沒有反應人口中症狀的普及性。

結果：總共114名參與研究，最終分析了77份完整案例，37份案例中途退出。人口統計分析顯示，男性／女性：41／36，平均年齡28.6歲。當中有65份 (84.4%) 「臨床上的成功」案例，以及由醫生主觀地判斷的12份 (15.6%) 失敗案例。憑經驗考慮，每種從列表中挑出的症狀都至少指引出兩個可能的處方。

結論：識別出由順勢療法研究中央委員會 (CCRH) 出版的驗證記錄中的16個症狀，也證實了由其他文獻中得出的4個症狀。鑒別出51個新臨床症狀／症狀組成部分。在實務設定中進一步複製和評估可能性比率，對於確認和納入這些在順勢療法文獻中的症狀非常重要。

關鍵字：隊列、臨床認證、芒果、順勢療法、觀察性研究。

