A multicentric, double-blind randomized, homoeopathic pathogenetic trial of *Allium sativum*

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ABSTRACT

**Background:** Homoeopathic drug proving is an integral part of Homoeopathic System of Medicine. It is the first step in finding out the pathogenetic powers of a drug.

**Objective:** To elicit the pathogenetic response to *Allium sativum* in homoeopathic potencies on healthy human provers.

**Materials and Methods:** A multi-center randomized, placebo-controlled, double-blind trial was conducted at two centers of the Central Council for Research in Homoeopathy (CCRH). Proving was conducted on 33 healthy provers after the pretrial medical examination. All the provers were given 12 doses of placebo divided in 4 doses/day for 3 days during the first phase of the trial. After randomization, in the intervention group (21 provers), *Allium sativum* (*A. sativum*) was proved in 6C and 30C potencies, in two phases. In the placebo group, 12 provers were administered placebo in the same manner. The symptoms manifested during the trial period were noted down by the provers and then elaborated by the proving masters. The generated data on *A. sativum* were then compiled and analyzed at proving-cum-data processing cell at CCRH headquarters.

**Results:** Out of 21 provers who were on actual drug trial, only nine provers manifested symptoms. Drug was able to manifest symptoms in both the potencies, in more or less every part of the body.

**Conclusion:** The pathogenetic response elicited during the proving trial expands the scope of use of the drug *A. sativum* and will benefit the research scholars and clinicians. The generated symptoms of this drug will carry more value when verified clinically.

**Keywords:** *Allium sativum*, Double blind, Drug proving, Homoeopathic pathogenetic trial, Homoeopathy, Pathogenetic effect, Placebo

INTRODUCTION

*Allium sativum* L., commonly known as garlic, is one of the key ingredients of spices used in every house. Its medicinal properties have been known since ancient...
times. It was used for dressing wounds during the First World War. In the 16th century B.C., the Egyptians used it in about 22 remedies for various ailments such as heart diseases, tumors, and insect bites etc. Wealthy Romans but gave it to their soldiers to make them strong. In today’s world, it is used as an antibiotic, expectorant, antidiabetic, and as an aid for expelling worms, reducing blood clotting, and lowering blood pressure. It is used in treating the infections, for example, bronchial and digestive. It is administered as a circulatory remedy and in diabetes.[1]

Hippocrates warned that garlic “causes flatulence,” a feeling of warmth on the chest and a heavy sensation in the head. In 1955, a Russian study found that garlic extracts bind heavy metals, thus aiding their elimination.[2]

It is used in Ayurveda, Unani.[3] It is known for its pungent, heating, oleaginous, tonic, aphrodisiac, fattening, digestive, and antihelminthic effects. appetizer, sharp taste, diuretic, carminative, alexipharmic effects. It is found to be useful in diseases of the eye, heart, low fevers, bronchitis, inflammation, piles, leucoderma, asthma, “vata,” lumbago, tumors, epileptic fits, thirst, and earache, inflammation, paralysis, pain in the body and joints, troubles of the spleen, liver, and lungs. chronic fevers, caries of the teeth, and thins the blood.

In Cambodia, the leaves are used in the treatment of asthma.[3] Chinese have reported in their trial that garlic can be successfully used for cryptococcal meningitis,[3] has anticarcinogenic activity, antitubercural activity against Mycobacterium tuberculosis in vitro and in vivo. antibacterial activity against shigellosis antiatherosclerosis activity, hepa-to-protective activityand anti-diabetic effect. Handling of garlic for cooking causes contact dermatitis.[4] Garlic also demonstrated ameliorative effects in acute lepromatous neuritis.[5]

Toxicity studies of garlic extract and garlic oil revealed a significant rise in urea and alkaline phosphatase in serum.[4] The signs and symptoms of acute overdose of garlic as herbal medicine includes dizziness, light-headedness, burning sensation of mouth, haematomata, nausea, sweating, leukocytosis, anorexia, diarrhea, emesis, and menorrhagia. It can exacerbate bleeding in patients taking aspirin or anticoagulants.[2]

Garlic as a drug, “Allium sativum” was introduced in Homoeopathic Materia Medica proved in France by Petroz and Teste, 1852.[6] Homoeopathic drug proving is an integral part of Homoeopathic system of medicine. This is the first step in finding out the pathogenetic powers of a drug. As the extensive proving of this drug have not been done therefore, a systematic homoeopathic pathogenetic trial (HPT) of the drug in homoeopathic potencies to elicit its pathogenetic power was carried out by the Central Council for Research in Homoeopathy (CCRH) at two of its centers as per the approved protocol.

**Description**

An acaulescent, bulbous, hardy perennial herb, cultivated as an annual, up to 60 cm in height. Bulbs ovate, flattened below, tapering upward and compound, i.e. composed of small bulblets. Stem much reduced (disc), convex-conical, internodes very compressed from where fleshy scale leaves arise, a bud present at the apex from which flowering scape develops. Leaves are linear, flat, lanceolate, scape slender, spathe one-leaved, long, pointed, head-bearing bulbs, and flowers in umbel. Flowers small, white; perianth trimerous with six petals, segments lanceolate, acuminate; stamens six, filaments of inner whorl tricuspidate; ovary trigonous, trilocular, style filiform. Fruit is a capsule.[7,8]

**Botanical Name:** *Allium sativum* L.

**Family**[3]: Alliaceae (Liliaceae)

**Order** : Asparagales

**Common names**[3,5]

- **Hindi**: Lasan
- **Sanskrit**: Arishtha, Bhutabhna, Dirghapatraka
- **Bengali**: Rasun
- **Tamil**: Vellaipundu
- **English**: Garlic, Churl’s Treacle, Poor man’s treacle
- **Arabic**: Saum, Taum
- **Chinese**: Suan, suan T’eou, Ta Suan
- **German**: Knoblaunch, lauch

**Chemical**: Volatile oil (e.g. allyl alcohol, alliin, alliinase, allicin), scordinins

**Constituents**[1,2]: Selenium, Sulphur, and Selenium-containing compounds, Vitamins A, B, C, and E.

**Distribution**: Native of Mediterranean region, cultivated universally[7,8]

**Part used**: Mature bulbs.[7,8]
MATERIALS AND METHODS

Study Design and Study Setting
A randomized, double-blind, placebo-controlled study was conducted at the Central Research Institute (Homoeopathy), Kottayam and Central Research Institute (Homoeopathy), Noida.

Subjects
Selection of provers: Applications were invited from 15 to 20 volunteers of both sexes and age 18 years and above through “notice” placed on the notice board of the institutes and homoeopathic colleges. The volunteers of non-homoeopathic background were also considered for the study. Pretrial medical examination (PME) was then conducted for all the volunteers after getting written informed consent from them. Detailed physical, pathological, and radiological examinations were conducted by the medical experts to ensure the health status of the volunteers.

Inclusion Criteria
• Age: 18 years and above
• Sex: Both male and female
• Health status: Experts acceptance and certifying the volunteer is healthy
• Volunteer must be 2 months clear of any homoeopathic medicine and no change in health status in last 3 weeks
• Volunteer to be intelligent enough to record carefully the facts, subjective, and objective symptoms generated by the drug during proving.

Exclusion Criteria
• Volunteers suffering from any acute or chronic disease
• Volunteers under any kind of medical treatment
• Hysterical or anxious persons

The volunteer declared healthy by the medical experts were then enrolled as a prover. For the pathogenetic drug trial of Allium sativum, a total of 33 volunteers (medical students) were enrolled as provers.

Sample size
According to the drug-proving protocol of the Council, there should be at least 15 provers at one center, 30% of whom will act as control. Therefore, out of 33 provers, 21 were on verum and 12 were on placebo of both these centers. [Figure 1]

Proving Symptoms
The sign(s) and/or symptom(s) generated by verum (drug) or placebo (control) on each prover are noted down with stage, number of doses after which each of the signs or symptoms appeared, and the duration for which they persisted. The sign(s) and/or symptom(s) generated by verum group are separated from those generated by provers of control group. The sign(s) and/or symptom(s) which were produced by the placebo as well as the drug in provers are not taken into consideration.

Classification of Symptoms
• RS: Recent symptoms, i.e. a symptom that you are suffering from now or have been suffering from in the last year
• NS: New symptom

No. of volunteers screened = 42
No. of volunteers excluded = 09
They were excluded due to various pathological findings
Enrolled = 33
Randomization
Symptoms developed in 9 provers
Verum = 21
Control = 12
Symptoms developed in 8 provers

Figure 1: Flow chart of study participants
• OS: Old symptom. State when the symptom occurred previously
• AS: Alteration in present or old symptom (e.g. used to be left side, now on the right side)
• US: An unusual symptom.

**Duration of Study**

**Ethics and Consent**
The Council’s Ethical Committee approved the study protocol. Proving masters with experience in drug proving were sensitized about the protocol. Written informed consent was received from all the volunteers prior to enrollment in the study.

**Procedure**
The study was conducted in three phases at each of the centers. In each phase, 12 doses of drug or placebo as per randomization were administered, divided in 4 doses/day for 3 days (if no symptom arises).

1. Phase I: Placebo phase. All the provers were given placebo in Phase I. It is useful in generating prover’s response to placebo in both the groups and therefore symptoms generated by the prover in this stage act as control for subsequent phases
2. Phase II: In 2nd phase, the verum group received the drug in 6C potency and placebo group received optically identical placebo
3. Phase III: In 3rd phase, the verum group received the drug in 30C potency and placebo group received optically identical placebo.

At each study center, a proving master supervised the volunteers enrolled in the study. After receiving the informed consent, PME, the baseline characteristics equivalent to homoeopathic interview, and the findings with respect to all the systemic examination and laboratory investigations were filled in the Proforma. The volunteers were instructed to take four globules of the coded drug 4 times a day for 3 days maximum. The provers were asked to note down daily the details of their feelings/changes in mental and/or physical level, after taking the coded drug in “Prover’s Day Book Proforma.”

**If No Sign(s)/Symptoms(s) Appeared**
The provers noted down “no symptom” with date and time of intake of the respective dose of the drug/placebo in “Prover’s Day Book Proforma.”

Before commencing the administration of subsequent potencies (subsequent phase) of the drug, the provers remained on a washout/rest period for 30 days and started taking next potency following the same procedure as mentioned above, till completion of all the doses/appearance of symptom. The same procedure was followed for the 3rd phase. After completion of trial of all potencies, the provers underwent terminal medical examination (TME).

On completion of all the phases of the drug proving, the compilation of data recorded in “Prover’s Day Book Proforma,” “Symptoms Elaboration Proforma,” “Pathological Report Sheets,” and “TME sheets” was done by the drug proving-cum-data processing
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cell at the Council’s headquarters. After decoding, the sign(s) and/or symptom(s) generated by the provers kept on the drug were separated from those generated by the provers kept on placebo.

Randomization and Blinding
Provers were randomized in two groups, Group I (n = 21): Homoeopathic group and Group II (n = 12): Placebo group. Random numbers were generated with the help of computer-based software available at http://www.randomizer.org (accessed in August 2011) and the random code was kept at CCRH headquarters. The decoding of the group was done after the compilation of the symptoms produced in both the groups.

Both homoeopathic drug and placebo were made in identical form so indistinguishable. Provers and the investigators were kept blinded to the group allocation and also to the identity of the drug. All the provers were assigned code numbers, and coded drugs of different potencies were supplied in separate glass phials, bearing code numbers of the respective prover.

Intervention
Homoeopathic group
About 100 ml sealed bottles of A. sativum in 6C and 30C were procured from a GMP-certified homoeopathic drug manufacturer in India. Globules of number thirty were medicated with these attenuations at the CCRH headquarters office.

Placebo group
Placebo was made up of un-medicated globules (number thirty) moistened with un-medicated dispensing alcohol (unsuccussed) and was therefore indistinguishable from Verum.

Management of Adverse Effects
A vial of medicated globules of Camphora 30C was sent with each quota to each center as “antidote” as it is believed to antidote nearly every vegetable medicine. In case of prolonged or intensely disturbing symptoms, antidote was to be used by the proving master after consulting the medical expert.

Statistical Analysis
Statistical analysis was done by using IBM SPSS 20.0. Comparison between Homoeopathy and placebo groups were performed at baseline to assess randomization effect using independent “t-test” for continuous variables and Chi-square test for categorical variables. Changes from the PME to TME in the pathological variables of body mass index (BMI), haemoglobin (Hb), erythrocyte sedimentation rate (ESR), fasting blood sugar (FBS), total cholesterol, serum urea, serum glutamate oxaloacetate transferase (SGOT), and serum glutamate pyruvate transferase (SGPT) were calculated by independent “t-test.” In all the analyses, P < 0.05 was considered significant.

Pathogenetic Effects
Pathogenetic effects (proving symptoms) are defined as all changes in the state of health and laboratory findings reported by the provers during the HPT and recorded in the final report. The incidence of pathogenetic effects per prover is defined as the total number of findings observed in verum group of the trial divided by the total number of provers. Pathogenetic effects were deduced from:

i. Comparison of symptoms developed in placebo phase with symptoms during intervention phases (intraprover comparison)

ii. Comparison of symptoms developed by provers on control (for all phases) with provers on actual drug trial (interprover comparison).

RESULTS
A total of 33 healthy provers were enrolled. Out of whom, 30 provers underwent the Terminal Medical Examination (TME). 2 and 1 prover(s) were dropped out from the verum and placebo group respectively. Thus the data analysis was done on 30 provers. The flow of the patients in the study is given at figure 1. The baseline information in both the groups were comparable [Table 1]. Though there was difference in FBS at baseline between the groups but they were within normal limits.

During the pathogenetic trial, out of 21 provers who were in verum group, only 9 (42.85%) provers reported symptoms consequent upon the administration of the drug. In the placebo group, 8 (66.67%) provers reported the incidence of symptoms. The Chi-square test shows that there is no difference between the 6C and 30C groups for producing the symptoms (P = 0.068, confidence interval: −0.68 to −0.019). The symptoms were observed from both the potencies, i.e. 6C and 30C. Out of 23 symptoms which were produced by the provers of verum group in 2nd and 3rd phases, 14 symptoms were produced in 6C potency [Table 2] whereas nine symptoms were produced in 30C potency [Table 3].
The present study shows that there is no statistically significant difference between the pathological variables of Hb, ESR, FBS, total cholesterol, blood urea, SGOT, and SGPT in the PME and TME of the verum and placebo groups. In BMI, mean changes occurred in the verum group from PME at 20.7 ± 2.8 to 20.8 ± 2.9 at TME and in control group from PME at 23.2 ± 4.3 to 23.3 ± 4.2 at TME. In verum group, Hb values decreased from 12.5 ± 1.5 to 11.9 ± 1.3 and in control group, changes noticed from PME at 13.3 ± 1.8 to 12.7 ± 1.6 at TME. Statistically, there is no difference between PME and TME in BMI and Hb [Table 4].

Intragroup analysis was done considering the physical built, physical generals, and mental generals of the provers in verum group who have produced symptoms, but no significant similarities were found in these provers. Further, intergroup analysis considering the above parameters was done in the provers who have produced symptoms in the verum group and control group. There were no significant similarities or dissimilarities found.

A comprehensive qualitative symptom profile of intervention group, control group, and former homoeopathic-proving symptoms found in literature[11-13] [Table 5] reflect that:

- No symptoms were generated in intervention group in regional spheres of mind, eye, ear, mouth, teeth, throat, rectum, and skin in the present study, although they are present in the literature
- In present and previous proving, the common regional affinities were found in head, nose, face, stomach, abdomen, chest, back, extremities, and generalities.

The number of symptoms developed in control (placebo) group was almost 3 times of those produced in the verum group. Some of the symptoms are different from those developed in verum group and few are overlapping. No adverse effect was observed during the trial; hence, antidote (Camphora) was not used.

### Table 1: Baseline information

<table>
<thead>
<tr>
<th>Variable</th>
<th>Homoeopathy (n=21)</th>
<th>Placebo (n=12)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td>22.1±1.2</td>
<td>22.0±1.4</td>
<td>0.83</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>4 (12.1)</td>
<td>5 (15.2)</td>
<td>0.16</td>
</tr>
<tr>
<td>Female</td>
<td>17 (51.5)</td>
<td>7 (21.2)</td>
<td></td>
</tr>
<tr>
<td>Weight (in kg)</td>
<td>53.4±9.3</td>
<td>56.7±14.8</td>
<td>0.47</td>
</tr>
<tr>
<td>BMI</td>
<td>20.7±2.8</td>
<td>23.2±4.3</td>
<td>0.05</td>
</tr>
<tr>
<td>Hb (g/dl)</td>
<td>12.5±1.5</td>
<td>13.3±1.8</td>
<td>0.13</td>
</tr>
<tr>
<td>ESR (mm after 1 h)</td>
<td>27.3±13.3</td>
<td>19.0±14.0</td>
<td>0.19</td>
</tr>
<tr>
<td>FBS (mg/dl)</td>
<td>85.9±11.3</td>
<td>83.6±10.2</td>
<td>0.02</td>
</tr>
<tr>
<td>Total cholesterol (mg/dl)</td>
<td>161.6±17.2</td>
<td>146.4±17.2</td>
<td>0.66</td>
</tr>
<tr>
<td>SBP (mm of Hg)</td>
<td>113.0±8.2</td>
<td>112.5±7.5</td>
<td>0.85</td>
</tr>
<tr>
<td>DBP (mm of Hg)</td>
<td>76.0±5.6</td>
<td>74.8±5.1</td>
<td>0.55</td>
</tr>
<tr>
<td>Blood urea (mg/dl)</td>
<td>20.4±6</td>
<td>21.6±8.2</td>
<td>0.66</td>
</tr>
<tr>
<td>SGOT (U/L)</td>
<td>5.1±5.6</td>
<td>5.3±5.8</td>
<td>0.94</td>
</tr>
<tr>
<td>SGPT (U/L)</td>
<td>13.1±2.4</td>
<td>11.6±2.8</td>
<td>0.29</td>
</tr>
</tbody>
</table>

SD: Standard deviation; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; Hb: Haemoglobin; FBS: Fasting blood sugar; SGOT: Serum glutamic oxaloacetic transaminase; SGPT: Serum glutamic pyruvic transaminase; ESR: Erythrocyte sedimentation rate

### Table 2: Symptoms produced in 6C potency

<table>
<thead>
<tr>
<th>Location</th>
<th>Symptoms observed</th>
<th>Doses</th>
<th>Symptom duration in days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td>Throbbing pain in right temporal region, agg. bright light, noise; amel. hard pressure, beating head with hand</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Sudden aching pain in forehead (remained for 2 h only)</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Mild pain on right side of forehead and in right eye, after half an hour pain spreads to whole head and both eyes followed by stitching pain in parietal region. Pain accompanied by nausea, heaviness in forehead. Pain relieved after bathing next day</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Piercing pain in forehead, extending to temples and ears. Forehead hot to touch</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Pain in left occipital region, amel. after sleep</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Nose</td>
<td>Coryza with sneezing, thick yellow nasal discharge, accompanied by nasal blockage, agg. in morning</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Stomach</td>
<td>Appetite increased</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Abdomen</td>
<td>Pain in epigastrium and lower abdomen, agg. traveling; amel. after sleep, drinking water</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Dry cough accompanied by tiredness and increased thirst</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Back</td>
<td>Aching pain in left scapular region, agg. raising arm, stooping</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Extremities</td>
<td>Aching pain in left elbow joint</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Fever</td>
<td>High fever with weakness and body ache</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Fever with stitching pain in forehead, agg. heat; amel. after sleep, tight bandage</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Generalities</td>
<td>Weakness with body ache more in lower abdomen amel. after sleep</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

agg.: Aggravation; amel.: Amelioration
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Among the symptoms manifested in verum group, headache was produced in six provers and in both potencies. Heaviness of head was manifested in only one prover after taking seven doses of 30C potency and this has been also cited in Homoeopathic literature.\[11,12,14\] All other symptoms were produced in single prover each. The incidence of pathogenetic effects in this study has been found to be 1.09.

### Symptoms Developed During Drug Proving (Control Group)

Each of these symptoms mentioned below were generated and reported by one prover.

1. **Mind:**
   - Difficulty in concentration (4, 1)\[Ψ\]

2. **Head:**
   - Headache in single spot left side. Pain was constant, severe, aching with heat of the single spot, \textit{amel}.
   - Pain in forehead with heaviness of head, accompanied with sleepiness, weakness, nausea and pain in eyes; \textit{amel}. after taking bath
   - Piercing pain on both sides of head, accompanied with pain in eyes, \textit{amel}. rest
   - Heaviness of head, remained for half an hour, \textit{amel}. Rest
   - Pain in right side of forehead, accompanied by heaviness of head, \textit{agg}. at midnight; \textit{amel}. after sleep

### Table 3: Symptoms developed by 30C potency

<table>
<thead>
<tr>
<th>Location</th>
<th>Symptoms observed</th>
<th>Doses</th>
<th>Symptom duration in days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td>Sudden aching pain in forehead, \textit{agg}. noise; \textit{amel}. tight bandage</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Pain in forehead with heaviness of head, accompanied with sleepiness, weakness, nausea and pain in eyes; \textit{amel}. after taking bath</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Piercing pain on both sides of head, accompanied with pain in eyes, \textit{amel}. rest</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Heaviness of head, remained for half an hour, \textit{amel}. Rest</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Pain in right side of forehead, accompanied by heaviness of head, \textit{agg}. at midnight; \textit{amel}. after sleep</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Face</td>
<td>Nonitching macular eruptions on face. Later eruptions with dryness, \textit{agg}. evening, washing with warm water. Eruptions subsided, leaving dryness on the area</td>
<td>12</td>
<td>17</td>
</tr>
<tr>
<td>Stomach</td>
<td>Nausea, \textit{amel}. drinking water</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Chest</td>
<td>Painful, red boil in axilla</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Extremities</td>
<td>Stitching pain in right forearm, \textit{agg}. pressure, lying on affected side; \textit{amel}. rest</td>
<td>12</td>
<td>4</td>
</tr>
</tbody>
</table>

- **Table 4: Comparative investigational values of both the groups**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Homoeopathy (n=19)</th>
<th>Placebo (n=11)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PME</td>
<td>TME</td>
<td>PME</td>
</tr>
<tr>
<td>BMI (g/dl)</td>
<td>20.7±2.8</td>
<td>20.8±2.9</td>
<td>23.2±4.3</td>
</tr>
<tr>
<td>Hb (g/dl)</td>
<td>12.5±1.5</td>
<td>11.9±1.3</td>
<td>13.3±1.8</td>
</tr>
<tr>
<td>ESR (mm after 1 h)</td>
<td>27.3±13.3</td>
<td>25.9±20.1</td>
<td>19.0±14.0</td>
</tr>
<tr>
<td>FBS (mg/dl)</td>
<td>85.9±11.3</td>
<td>87.5±15.2</td>
<td>83.6±10.2</td>
</tr>
<tr>
<td>Total cholesterol (mg/dl)</td>
<td>161.6±17.2</td>
<td>165.6±24.6</td>
<td>146.4±17.2</td>
</tr>
<tr>
<td>Blood urea (mg/dl)</td>
<td>19.9±5.8</td>
<td>25.1±4.6</td>
<td>21.3±8.1</td>
</tr>
<tr>
<td>SGOT (U/L)</td>
<td>5.1±5.6</td>
<td>16.7±11.7</td>
<td>5.3±5.8</td>
</tr>
<tr>
<td>SGPT (U/L)</td>
<td>13.1±2.4</td>
<td>13.4±9.3</td>
<td>11.6±2.8</td>
</tr>
</tbody>
</table>

Statistically significant at \(P<0.05\); Which has been shown after comparing between the groups. BMI: Body mass index; Hb: Haemoglobin; FBS: Fasting blood sugar; SGOT: Serum glutamic oxaloacetic transaminase; SGPT: Serum glutamic pyruvic transaminase; ESR: Erythrocyte sedimentation rate; FBS: Fasting blood sugar; PME: Pretrial medical examination; TME: Terminal medical examination

\[\Psi\] In parenthesis, the first number denotes number of doses after which that particular symptom was produced and the second number denotes the duration (in days) for which the symptom lasted.

Among the symptoms manifested in verum group, headache was produced in six provers and in both potencies. Heaviness of head was manifested in only one prover after taking seven doses of 30C potency and this has been also cited in Homoeopathic literature.\[11,12,14\] All other symptoms were produced in single prover each.

The incidence of pathogenetic effects in this study has been found to be 1.09.

### Symptoms Developed During Drug Proving (Control Group)

Each of these symptoms mentioned below were generated and reported by one prover.

1. **Mind:**
   - Difficulty in concentration (4, 1)\[Ψ\]

2. **Head:**
   - Headache in single spot left side. Pain was constant, severe, aching with heat of the single spot, \textit{amel}. cold application (6, 1)
   - Sudden aching pain in frontal region with burning in eyes, \textit{amel}. pressure (1, 1)
   - Aching pain in frontal region with burning in eyes (2, 1)
   - Headache with heaviness in frontal and vertex regions, \textit{amel}. closing eyes (12, 3)
   - Aching pain in temporal region, \textit{amel}. pressure (9, 3)
   - Pulsating pain in right temporal region, \textit{amel}. by pressure (6, 1)
   - Pulsating pain in left parietal region, \textit{agg}. talking; \textit{amel}. open air (10, 1)
   - Aching pain in occipital region with increased thirst and decreased appetite. Pain \textit{agg}. stooping (10, 1)
   - Pain in right occipital region, stretching and pulling sensation, \textit{agg}. stooping, laughing; \textit{amel}. keeping head still, straight (6, 6)
   - Heaviness of head, \textit{amel}. bathing (8, 2)
   - Stitching pain in right temporal region, \textit{amel}. Sleep, rubbing (4, 1)
   - Pain in forehead extends to right frontal region (9, 1)
Manchanda, et al.: Homoeopathic Pathogenetic Trial of Allium sativum

- Piercing pain in right side of forehead (8, 1)
- Aching pain in occipital and parietal region, _agg._ noon, evening; _amel._ tight bandage. Then, aching pain in forehead (5, 2)
- Dull pain in frontal region of head, _amel._ lying down, pressure (7, 1)
- Dandruff with itching - white powder falling while scratching head (8, 3).

3. Eye:
- Pain in right eye, _agg._ while reading (8, 1).

4. Ear:
- Pain in right ear (8, 1)
- Stitching pain in right ear extends to right shoulder (9, 1)
- Pain in ears (3, 1).

5. Nose:
- Coryza, watery, profuse, bland, nasal discharge with incessant sneezing in bouts of 5–6 sneeze within 2–3 min interval, _agg._ cold water; _amel._ hot drinks and food. It is accompanied with smarting in eyes with watery discharge (12, 3)
- Running nose (3, 1).

6. Mouth:
- Dryness in the middle of tongue, tongue sticks to upper palate, no relief after drinking water, _agg._ afternoon. It is accompanied with rumbling sensation in abdomen with urge to stool; _amel._ after passing stool (6, 4)
- Dryness of mouth (8, 2)
- White coating on tongue (4, 1)
- Pain in gums on posterior part of lower jaw beyond wisdom tooth followed by redness and inflammation, _agg._ swallowing liquid. Pain extends to neck (9, 6).

7. Teeth:
- Pain in right premolar teeth (4, 1).

8. Face:
- Open comedones on left cheek, _agg._ afternoon (12, 1)
- Small red eruption on face with slight itching (12, 2)
- Boil on face (12, 1).

9. Throat:
- Sore throat, _amel._ warm drink. It is accompanied with dry cough, feverish feeling (5, 1)
- Sore throat, _amel._ warm drink. It is accompanied with cough, coryza, chest pain and heaviness, expectoration yellow, profuse, strain to expectorate the sputum (5, 2)
- Aching pain in throat. It is accompanied with dry cough and sneezing (5, 5)
- Pain in throat with tired feeling (3, 2).

10. Stomach:
- Desire to eat chicken but unable to eat at night (6, 1)
- Loss of appetite (4, 1).

11. Abdomen:
- Aching pain in lower abdomen had to rush to stool with increased gas formation, _amel._ passing stool (6, 1)
- Cramping pain in abdomen with sudden urge for stool (2, 1)
- Indigestion with flatulence, rumbling followed by loose, watery stool (2, 1)
- Stretching pain in lower abdomen (12, 1).

12. Rectum:
- Diarrhea, loose, watery stool, hot. It is accompanied with burning in rectum during stool (prover took momos last night) (4, 2)
- Diarrhea, yellow, watery, forcefully had to rush to toilet with rumbling and gushing (prover ate chicken in the dinner) (4, 1)
- Loose stool with rumbling in abdomen reoccurring after passing stool (6, 4).

13. Back:
- Pain in scapular region (9, 1)
- Aching pain in lumbo-sacral region (11, 2).

14. Extremities:
- Aching pain in right hand near wrist, _agg._ movement; _amel._ pressure. Pain radiates upward and downward (4, 2)
- Aching pain in wrist, _agg._ movement. Pain radiates upward and downward (8, 1)
- Aching pain in right knee, _amel._ tight bandaging (5, 1)
- Pustular eruption, redness around pustule slightly painful, tenderness in left leg. Pain radiates to right leg (5, 2)
- Pustular eruption on right leg (12, 3)
- Itching in sole of left foot, left knee, which becomes raw and sore (12, 1)
- Itching in left index finger (12, 1)
- Small red eruption with slight itching on right leg and right forearm (12, 1)
- Itching in whole body, _amel._ cold application (1, 1)
- Itching and small red eruption on leg with yellow urine (2, 4)
- Small pustular eruption on lateral side of middle finger of right hand (2, 1)
- Sudden, aching pain in left wrist joint, with sensation as if wrist would break, _agg._ pressure; _amel._ tight bandaging (12, 5)
• Shoulder pain with tired feeling with fever (13, 1)
• Aching pain in left shoulder, agg. lifting things; amel. lying on left side and pressure (3, 2)
• Peeling of skin of both hands, agg. morning (3, 2).

15. Fever:
• Fever (Temp. 103°F) accompanied with coryza, body ache, chill, sweating, and increased frequency of urine. Fever decreased to 100°F after sweating (12, 2).

16. Skin:
• Slight itching all over the body more on scalp, remained the whole day (12, 1).

17. Generalities:
• Weakness with body ache (8, 1).

DISCUSSION

In the present study, when the symptoms generated in the verum group were compared with the earlier proving symptoms available in the Homoeopathic literature, it was found that symptoms were related to:

**Head**
Dyspeptic subjects as per prior proving are similar to headache with nausea and other gastric disturbances in the present study. Similarly, heaviness of head preventing opening the eyes is also found in this study.

**Face**
The eruptions in the earlier proving were related to herpes and also having facial neuralgia, but in the present study, no herpes eruptions appeared, rather there are nonitching macular eruptions.

**Stomach and Abdomen**
Nausea and increased appetite found in present study are similar to those found in the previous proving. Besides these symptoms, the proving data in older literature has much more in store related to digestive system. There are symptoms related to pain in the epigastrium and hypogastrium in the present study, whereas in the literature, there are colicky symptoms in various parts of the abdomen with flatulence and borborygmi.

**Respiratory System**
The nasal symptoms, coryza and nasal blockage, are similar in the present and older literature, but the characteristics of discharges are different, as in older literature, there is dry coryza and epistaxis, whereas in the present study, there is thick yellow discharge from nose. Symptoms of cough with and without expectoration are found in the literature, but in the present study, dry cough with tiredness and increased thirst have been noted.

**Chest, Back, and Extremities**
Symptoms have been generated related to these anatomical regions in the present study and on comparison with older literature, it has been found that:

The symptoms related to eruptions on chest are found in the present study and older literature. However, other symptoms found in the previous proving are not found in the present study.

Under back, the old literature mentions about the symptoms related to the nape of neck, sacrum, coccyx, and even related to the skin, but in the present study, only the symptoms related to pain in the scapular region have been found.

In the extremities section, the present study has symptoms related only to the upper extremities, whereas the older literature has symptoms related to upper and lower extremities involving the joints as well.

**Fever**
In the older proving, it has been found that fever has all the three stages of fever, i.e. chill, heat, and sweat; but in the present study, there is no detailing found.

**Generalities**
The general weakness and lassitude along with the body ache in different parts of the body are seen in both, in the present and previous provings.

It has been noted that number of symptoms has been produced in both the groups along with a wide range of overlapping of symptoms, but still there were symptoms exclusive of *A. sativum* distinguishing it from the placebo. There is always a scope to improve upon and the parameters for defining the symptoms as characteristic, old and new symptoms may be incorporated. This will be an aid for better qualitative and quantitative analysis of the primary outcome of the study.

In one of the articles, Teut *et al.*[15] has mentioned that placebo proving occasionally seem to produce similar symptoms to the proving symptoms, thus casting further doubt on the use of this medium in proving’ and has attributed it to nocebo effect. A nocebo response is explained as subject’s own
### Table 5: Qualitative symptom profiles of intervention group, control group, and former homoeopathic drug-proving symptoms

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<tbody>
<tr>
<td>Mind</td>
<td>Difficulty in concentration</td>
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<tr>
<td>Head</td>
<td></td>
<td>Sudden aching pain in frontal region of head lasting for 2 h only. Mild headache on right side of frontal region and on right eye after half an hour pain in whole head and eyes. Then, stitching type of pain in parietal region. It is accompanied with nausea, heaviness in forehead. The complaints relieved after bathing next day.</td>
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<td>Sudden aching pain in frontal region of head lasting for half an hour, <em>amel.</em> rest Heaviness of head.</td>
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<td></td>
<td>Heaviness of head lasting for half an hour, <em>amel.</em> rest</td>
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<td>Catarhal ophthalmia at night; smarting, burning lachrymation; agglutination; returns every night when he tries to read. Tarsisore with irritation.[15] Could read only with spectacles; heaviness in eyes. Profuse watering of eyes without coryza.[158]</td>
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<thead>
<tr>
<th>Section</th>
<th>Placebo (C)</th>
<th>Allium sativum 6C (A1)</th>
<th>Allium sativum 30C (A2)</th>
<th>Symptoms produced by intervention ([A1+A2]−C)</th>
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<tbody>
<tr>
<td>Ear</td>
<td>Pain in ears.</td>
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<td>Pain in right ear.</td>
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<td></td>
<td>Stitching type of pain in right ear extending to right shoulder.</td>
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<td>Nose</td>
<td>Coryza, watery, profuse, bland, nasal discharge with incessant sneezing in bouts of 5-6 sneeze within 2-3 minutes interval, agg. cold water; amel. hot drinks and food. It is accompanied with smarting in eyes with watery discharges. Running nose.</td>
<td>Coryza with sneezing, agg. morning. It is accompanied with nasal blockage with thick yellow nasal discharge.</td>
<td>Coryza with sneezing, agg. morning. It is accompanied with nasal blockage with thick yellow nasal discharge.</td>
<td>Coryza dry rather than fluent, with pressive pain above the root of the nose. On blowing nose, blood from nose at night. Increased secretion of nasal mucus with slight blockage of both nostrils. Ozaena, smarting at junction of alae nasi and face, mostly left.</td>
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<td>Face</td>
<td>Open comedones on left cheek, agg. afternoon.</td>
<td>Nonitching macular eruptions on face.</td>
<td>Nonitching macular eruptions on face.</td>
<td>Lancinations on one side of the face. Dry lips. Smarting, itching; spots in upper face. Stinging in one side of face. Smarting as from herpetic eruptions near left angle of lips.</td>
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<td></td>
<td>Small red eruption with slight itching.</td>
<td>Later eruptions with dryness, agg. evening, washing with warm water. Eruptions subsided, leaving dryness on the area.</td>
<td>Later eruptions with dryness, agg. evening, washing with warm water. Eruptions subsided, leaving dryness on the area.</td>
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<td>Boil on face.</td>
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<tr>
<td>Mouth</td>
<td>Dryness in middle of tongue, tongue sticks to upper palate, no relief in spite of drinking water, agg. afternoon. It is accompanied with rumbling sensation in abdomen with urging to stool; amel. After passing stool. Dryness of mouth. White coating on tongue. Pain in gums on posterior part of lower jaw beyond wisdom tooth followed by redness and inflammation, agg. swallowing liquid. Pain extending to neck.</td>
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<td>Swelling of lower gums. Troublesome feeling during the night and in the morning, as of a hair on her tongue; renewed on waking. Tongue pale-red with effaced papillae. Dryness of palate. Very copious flow of sweetish saliva into the mouth in the forenoon, after meals; more especially after supper and during the night. Hot taste in mouth, proceeding from throat, strongly reminding him of garlic, immediately after taking the medicine and returning after breakfast to such a degree as to cause a flow of saliva. The symptoms of mouth are agg. by reading. Scurvy. Tongue furred white, with a disagreeable taste. Tongue dry at night. Sores in mouth.</td>
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<td>Teeth</td>
<td>Pain in right premolar teeth.</td>
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<td>Throat</td>
<td>Sore throat, <em>amel.</em> warm drink. It is accompanied with dry cough, feverish feeling. In another prover, it is accompanied with cough, coryza, chest pain and heaviness, expectoration yellow, profuse, strain to expectorate the sputum. Aching pain in throat. It is accompanied with dry cough and sneezing. Pain in throat and tired feeling.</td>
<td>Appetite increased.</td>
<td>Nausea, <em>amel.</em> drinking water.</td>
<td>Appetite increased. Nausea, <em>amel.</em> drinking water.</td>
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<tr>
<td>Stomach</td>
<td>Desire to eat chicken but unable to eat at night. Loss of appetite.</td>
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<td>Abdomen</td>
<td>Cramping pain in abdomen with sudden urge for stool. Indigestion, flatulence, rumbling followed by loose, watery stool. Aching pain in lower abdomen had to rush for stool with increased gas formation, <em>amel.</em> passing stool. Stretching pain in lower abdomen.</td>
<td>Pain in epigastrium and lower abdomen, <em>agg.</em> travelling; <em>amel.</em> sleep, drinking water.</td>
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<tr>
<td>Cough</td>
<td>Dry cough accompanied by tiredness and increased thirst.</td>
<td>Dry cough accompanied by tiredness and increased thirst.</td>
<td>Painful irritation of windpipe when coughing. Scraping in larynx exciting dry cough. Cough seeming to come from stomach. Cough giving rise to perceptible fetid smell. Dry cough after eating. Morning cough, after leaving his bedroom, with extremely copious mucous expectoration. Sudden paroxysms of hard, dry cough while smoking, compelling him to desist. Great difficulty in expectorating a glutinous mucous. Expectoration of thin, yellowish, purulent-looking blood-streaked mucous of putrid odor. Cough, agg: bending head; after eating; by open air.&lt;sup&gt;[12]&lt;/sup&gt; Deep-seated cough. Expectoration increased.&lt;sup&gt;[12]&lt;/sup&gt; Pain in left chest with dark urine. Darting pain in the chest which prevents sleep.&lt;sup&gt;[12]&lt;/sup&gt; Oppression of the chest during sleep. L lancinations in one side of the chest. Twitching pain in the side of the chest; it seems to him as if there was an empty spot in his chest. Lancinations under the shoulder blades and pectoral muscles increasing during the cough and deep inspirations, and becoming spasmodic if the latter are renewed several times in succession; with irresistible impulse to cough. Null stitches in right mamma. Stitches in pectoral muscles and beneath scapulae. Breasts swell after weaning. Swelling of breasts, sensitive to touch. Eruptions of red blotches between the breasts and around the nipples.&lt;sup&gt;[11,12]&lt;/sup&gt; Tension of the pulse and palpitation.&lt;sup&gt;[11,12]&lt;/sup&gt;</td>
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<tr>
<td>Chest</td>
<td>Painful, red boil in axilla.</td>
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<tr>
<td>Extremities</td>
<td>Peeling of skin of both hands, agg.</td>
<td>Aching pain in left elbow joint.</td>
<td>Stitching pain in right forearm, agg. pressure, lying on affected side; amel. rest.</td>
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<td>Morning.</td>
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<td>Itching in left index finger.</td>
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<td>Itching and small red eruption on leg with yellow urine.</td>
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<td>Small pustular eruption on lateral part of middle finger of right hand.</td>
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<td>Pustular eruption, redness around pustule</td>
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<td>slight painful, tender on left leg. Pustular eruption in right leg.</td>
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<td>Itching in sole of left foot, left knee, which became raw and sore.</td>
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<td>Shoulder pain and tired feeling with fever.</td>
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<td>Sudden, aching pain in left wrist joint, with sensation as if wrist would break, agg. pressure; amel. light bandaging.</td>
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<td>Aching pain in right hand near wrist, agg. movement; amel. pressure.</td>
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<td>Pain radiates upward and downward.</td>
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<td>Aching pain in right knee, amel. tight bandaging.</td>
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<th>Profile of Allium sativum by previous homoeopathic proving\cite{11-13}</th>
</tr>
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<tbody>
<tr>
<td>Fever</td>
<td>Fever (Temperature 103°F) accompanied with coryza, body ache, chill, sweating, and increased frequency of urine. Fever decreased to 100°F after sweating.</td>
<td>High fever with weakness and body ache. Fever with stitching pain in forehead, agg. heat; amel. after sleep, tight bandage.</td>
<td>Fever with increased temperature, weakness and body pain. Fever with piercing pain in frontal region, agg. heat; amel. sleep, tight bandage.</td>
<td>Chilliness on one side only. During coldness, redness of face. Vomiting during the fever. Sweat in afternoon. Sweat: acrid; causing itching; fetid.\cite{11,12} Shivering before midday and in evening.\cite{11,12} Chilliness from 1 day to another. Catarhal fever with predominant coldness. General heat during which there is distress. Heat during which she feels twitching in the limbs. Sweat of sour smell.\cite{11} Cold at night in bed. Chilliness and heat alternate, more evenings, hard pulse.\cite{11}</td>
<td>Chilliness on one side only. During coldness, redness of face. Vomiting during the fever. Sweat in afternoon. Sweat: acrid; causing itching; fetid.\cite{11,12} Shivering before midday and in evening.\cite{11,12} Chilliness from 1 day to another. Catarhal fever with predominant coldness. General heat during which there is distress. Heat during which she feels twitching in the limbs. Sweat of sour smell.\cite{11} Cold at night in bed. Chilliness and heat alternate, more evenings, hard pulse.\cite{11}</td>
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<td>Skin</td>
<td>Slight itching appeared all over body more on scalp, remained the whole day.</td>
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<tr>
<td>Generalities</td>
<td>Weakness with body ache.</td>
<td>General weakness. Next day, body ache, more in lower abdomen, amel. sleep.</td>
<td>General weakness. Next day, body ache, more in lower abdomen, amel. sleep.</td>
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negative expectations and/or negative suggestions from therapists/clinical staff in the absence of any treatment. Nocebo phenomena are generally explained by Pavlovian conditioning and expectations induced by verbal information and suggestions. In this trial also, nocebo phenomenon can be considered and apart from the individual’s own perception, this can be attributed to the discussion which usually takes place among the students of homeopathic colleges who are the participants in the study. This poses a limitation as it is difficult to keep a check on them for not discussing or sharing the experiences. The massive number of symptoms developed in control group could be considered because of such discussions among the students.

Some symptoms of head, skin, nose, extremities, etc., lasted for many days; this shows that drug has affinity toward these regions. Some symptoms appeared immediately after administration of few doses such as increased appetite after administration of 1st dose itself whereas symptoms of head, fever, and weakness appeared after administration of 5 doses or more. Skin symptoms which persisted for more than 17 days appeared after the administration of 12th dose.

In Boericke’s Materia Medica, A. sativum has been mentioned as weight gainer whereas in this proving of A. sativum, although BMI has increased, there is no statistically significant difference in the homoeopathic group and also in the control group. Studies have revealed that A. sativum can suppress the lipopolysaccharide inflammatory signals by generating an anti-inflammatory gene expression profile and by modifying adipocyte metabolic profile, which is considered in the treatment of obesity. In addition, the studies conducted on mice with S – methyl L – cysteine compound extracted from A. sativum have shown significant reduction in the animal weight.

Apart from BMI, other physiological parameters were also compared. Inter- and intra-group analyses were done and difference in the entry and end point was found, though not statistically significant.

As given in the background of this article regarding garlic in Ayurvedic context that it has action on the digestive system, fattening effects, and it is known to improve appetite, voice, complexion, and found to be useful in diseases of the eye and the heart, low fevers, bronchitis, inflammation, piles, leucoderma, asthma, lumbago, tumors, epileptic fits, earache. Similarly, in Unani system of medicine, it has diuretic effect and has been found to be useful in inflammation, paralysis, pain in the body and joints, troubles of the sleep, liver, and lungs. It clears the voice, found to be good for lumbago, chronic fevers, thirst, caries of the teeth, leucoderma, and thins the blood. In the present study, certain similarities have been found in the symptoms produced and also reported in the older homoeopathic literature. The usefulness of this drug in case of leucoderma, epileptic fits, paralysis, tumors, etc., which is not found in the present study can be explored further.

There are certain other limitations in the study apart from the nocebo effect such as unbalanced randomization allocation, no defined parameters to classify characteristic symptoms, and less number of provers.

CONCLUSION

The pathogenesis of the A. sativum found in this study has produced symptoms which were already noted in the Homoeopathic literature and there are many symptoms which are new. The research scholars such as postgraduate and PhD students, who wish to take up research studies on the drug A. sativum, can make this as one of the references and take up further studies. These signs and symptoms need to be subjected to clinical verification study for confirming there therapeutic utility and introducing them in the Homoeopathic Materia Medica and can be of help to clinicians.

Acknowledgement

The authors are indebted to Ms. Maya Padmanabhan, Statistical Assistant, Central Council for Research in Homoeopathy, New Delhi for doing the statistical analysis of the data. The provers who participated in the study are thankfully acknowledged.

Financial Support and Sponsorship

The study has been funded by Central Council for Research in Homoeopathy, an autonomous organization under Ministry of AYUSH, Govt. of India.

Conflicts of Interest

There are no conflicts of interest.

REFERENCES

Manchanda, et al.: Homoeopathic Pathogenetic Trial of *Allium sativum*

**RESUMEN**

**Fundamento:** La patogenia homeopática es parte integral de la medicina homeopática. Constituye el primer paso para conocer el poder patogénico de un medicamento.

**Objetivos:** Evidenciar la respuesta patogénica a las potencias homeopáticas de *Allium sativum* en personas voluntarias sanas.

**Materiales y métodos:** Se realizó un ensayo aleatorizado, a doble ciego, controlado con placebo, multicéntrico en dos centros del CCHR (Central Council for Research in Homeopathy, Consejo Central de Investigación en Homeopatía). Las patogenias se efectuaron en 33 voluntarios sanos después de un examen médico preensayo. En la primera fase del ensayo, todos los voluntarios recibieron 12 dosis de placebo divididas en 4 dosis al día durante 3 días. Tras la aleatorización, en el grupo de intervención (821 voluntarios), se examinó *Allium sativum* en las potencias de 6C y 30C, en dos fases. En el grupo placebo (12 voluntarios), se administró el placebo de la misma manera. Los examinadores registraron los síntomas manifiestos durante el periodo del ensayo y los directores del ensayo los elaboraron. Los datos generados sobre *Allium sativum* fueron recopilados y analizados en el centro de procesado *proving-cum-data* de la sede principal del CCHR.

**Resultados:** Únicamente 9 de los 21 voluntarios que tomaron el medicamento real manifestaron síntomas. Ambas potencias del medicamento dieron lugar a síntomas, en más o menos todo el organismo.

**Conclusiones:** La respuesta patogénica evidenciada durante la patogenia amplía el ámbito de indicaciones de *Allium sativum* y beneficiará a los becarios y los médicos investigadores. Los síntomas generados por este medicamento tendrán más valor cuando se verifiquen clínicamente.