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Effect of Orally Administered Potentized Capsaicin and Dihydrocapsaicin in Humans: A Homeopathic Pathogenetic Trial

Rajesh Shah

Life Force Homeopathy, Mumbai, India

Keywords
Capsaicin · Dihydrocapsaicin · Homeopathic pathogenetic trial · Drug proving · Potentization · Double-blind · Randomization · Placebo control · Pain · Safety · Symptoms

Schlüsselwörter
Capsaicin · Dihydrocapsaicin · Homöopathische pathogenetische Untersuchung · Arzneimittelprüfung · Potenzierung · Doppelblind · Randomisierung · Placebokontrolle · Schmerz · Sicherheit · Symptome

Summary
Background: A homeopathic pathogenetic trial is a procedure to examine the disease-producing effect of any substance on humans. Capsaicin and dihydrocapsaicin are known as pain-producing agents. According to the homeopathic law of similars, any substance having the capacity to produce certain symptoms should also be able to treat them in return, when administered in small (potentized) dose. **Methods:** In a double-blind, randomized placebo-controlled homeopathic pathogenetic trial with 22 volunteers, 15 received a combination of capsaicin and dihydrocapsaicin as a single remedy in 30c potency, while 7 received placebo. The volunteers' symptoms during 5 weeks were carefully noted as per protocol. The participants signed an informed consent, the study was approved by the ethics committee, and laboratory investigations were documented and safety measures adopted. **Results:** A preparation of orally administered ultra-high diluted capsaicin and dihydrocapsaicin unveiled qualitatively and quantitatively distinct symptoms, comparable with effects of the crude substance. Compared to placebo, the homeopathic preparation produced significant symptoms in healthy human volunteers. These findings can subsequently be used therapeutically. **Conclusion:** The administration of potentized capsaicin and dihydrocapsaicin combination produced symptoms of pain (and others) in healthy volunteers. This preparation can be applied therapeutically following a basic homeopathic principle. Further research to confirm the assumptions is warranted.

Zusammenfassung
Hintergrund: Eine homöopathische pathogenetische Untersuchung ist ein Verfahren, um die krankheitsauslösenden Effekte, die verschiedene Substanzen auf Menschen haben können, zu untersuchen. Für derlei Wirkungen sind beispielsweise Capsaicin und Dihydrocapsaicin bekannt. Entsprechend dem homöopathischen Ähnlichkeitssprinzip sollte jede Substanz, die Schmerzen erzeugen kann, diese auch lindern können, insofern sie in potenzierter Dosis verabreicht wird. **Methoden:** In einer doppelblinden, randomisierten placebokontrollierten homöopathischen pathogenetischen Untersuchung mit 22 Freiwilligen erhielten 15 Teilnehmer eine Kombination aus Capsaicin und Dihydrocapsaicin als Einzelpräparat (30c), 7 erhielten Placebo. Die Symptome wurden über einen Zeitraum von 5 Wochen beobachtet und dokumentiert. Die Teilnehmer gaben eine Einverständniserklärung ab, die Studie wurde vom Ethikkomitee genehmigt und die Laboruntersuchungen sowie Sicherheitsmaßnahmen dokumentiert bzw. ergriffen. **Ergebnisse:** Das Präparat aus oral verabreichtem hochverdünntem Capsaicin and Dihydrocapsaicin führte zu qualitativ und quantitativ unterschiedlichen Symptomen, vergleichbar mit Effekten der Substanz in unverdünntem Zustand. Verglichen mit Placebo führte das homöopathische Präparat bei den gesunden Probanden zu signifikanten Symptomen. Diese Ergebnisse könnten in der Folge therapeutisch relevant sein. **Schlussfolgerung:** Die Anwendung eines potenzierten Kombinationspräparats aus Capsaicin and Dihydrocapsaicin rief bei den Studienteilnehmern Schmerz- und andere Symptome hervor. Das Präparat könnte einem grundsätzlichen homöopathischen Prinzip folgend therapeutisch eingesetzt werden. Weitere Forschungen zur Überprüfung dieser Annahmen wären angebracht.

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Rajesh Shah, MD
Life Force Homeopathy
411 Krushal Commercial Complex
GM Road, Chembur, Mumbai 400 089, India
sanjivak@gmail.com

Introduction

Capsaicin ($C_{18}H_{27}NO_3$; CAS 404–86–4) and dihydrocapsaicin ($C_{18}H_{29}NO_3$; CAS 19408–84–5) are prominent pharmacologically active and pain-producing alkaloids [1], which stimulate pain receptors. Capsaicin has been used as a topical pain-relieving substance in conventional medicine [2]. We have explored it further to examine if a homeopathic preparation of both substances for oral administration can alleviate painful conditions by following the basic principle of homeopathy. According to the law of similars [3] introduced by Samuel Hahnemann, the founder of homeopathy, he recommends to 'choose a medicine which can itself produce affection similar to that sought to be cured'. As per method, in a homeopathic pathogenetic trial (HPT) [4, 5] the effects of potentized homeopathic preparation on healthy human volunteers are studied and carefully recorded under placebo-controlled, randomized double-blind conditions. Finally, these findings are compared with and prescribed for the set of symptoms in diseased individuals.

HPT

The study was conducted to evaluate the effect of orally administered potentized preparation of capsaicin and dihydrocapsaicin (capshydro coded as CP-010) on healthy human volunteers. The aim was to report the symptoms exhibited by volunteers in verum and placebo groups and to demonstrate the difference in symptoms, qualitatively as well as quantitatively. Further, we wanted to explore the symptoms as well as indications for potential therapeutic applications in a range of disease conditions.

Methods

The HPT was conducted as double-blind, randomized placebo-controlled [5] study from February 4 till April 9, 2012. The CP-010 was prepared as per homeopathic potentization method, with additional documentation of force parameters applied in the process. The drug was tested (proved) in 30c potency on 22 volunteers (4 females and 18 males) with a randomization ratio of 2:1. 15 volunteers were given the preparation and 7 volunteers were given matching placebo. 3 females received the drug and 1 female received placebo, according to a pregenerated (computerized program) random number table (fig. 1).

All volunteers signed informed consent. The subjects remained blind for randomization till the completion of the proving period, data compilation, and data entry. The volunteers were selected based on the inclusion and exclusion criteria as per protocol. The volunteers underwent pre-observation and post-observation investigations. Each volunteer took the preparation according to the protocol, and for run-in period placebo was administered for 1 week . The occurring symptoms during the trial period were recorded (up to 6 weeks) by the volunteers in a diary and were cross-examined and elaborated by the investigator. The investigator had compiled the data, and data entry in specific format was done. For further analysis, decoding (opening the blind) was done and the final report was generated.

Methodological Quality Index

Methodological Quality Index (MQI) [4] is based on key components of methodological quality including internal and external validity items. It includes aspects, such as randomization, inclusion and exclusion criteria, blinding, and criteria for selection of pathogenetic effects, with values ranging from 1 to 4 for each component, giving a range from 4 to 16. Scores were divided into 4 methodological classes, whereby class I is the worst and class IV is the best, with arbitrary cutoff points (≤6 for class I; 7–10 for class II; 11–13 for class III; ≥14 for class IV).

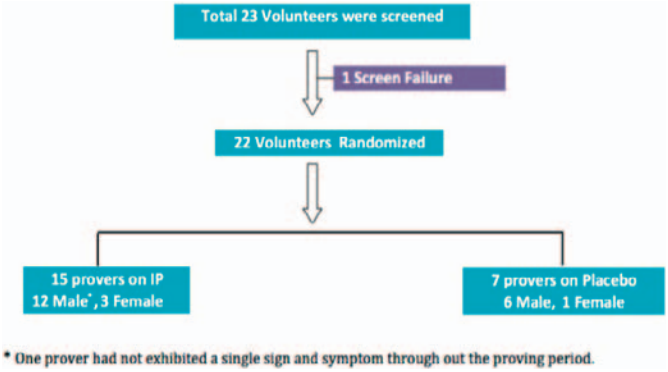

Fig. 1. CP-010 volunteers flow chart.

Randomization

A pregenerated (computerized program) random number table was used to allocate the randomization kits to the volunteers as per recruitment sequence (score 4).

Blinding

The study design contained double-blinding, i.e. participants and investigator was blinded till the end of proving period. The blinding was dissolved post-trial (score 4).

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria were clearly defined in the protocol (score 4).

Criteria for Selection of Pathogenetic Effects

During the symptom analysis, 6 criteria were defined:

1. All symptoms produced during run-in period and repeated by same volunteer in subsequent weeks (first week, with placebo) were excluded.
2. Symptoms produced by the volunteers who were dropped out from study due to adverse events were excluded.
3. Symptoms occurring in the placebo and in the study group were analyzed quantitatively as well as qualitatively over a period of 5 weeks. If control and study group experienced the same symptoms, we evaluated on the basis of intensity and duration, i.e. if headache was reported as mildly intense ($^{+}$) in the placebo group and as severely intense ($^{+++}$) in the drug group, it was also considered.
4. All symptoms were reported quantitatively and measured daily, embracing duration, frequency, and characteristics (e.g., dull headache with a feeling of heaviness in head associated with sleepiness (1 volunteer; 9^{+} (day 22 for 2–3 h).
5. Every symptom described by the volunteers has been graded as $^{+}$ (mild), $^{++}$ (moderate), $^{+++}$ (severe), and $^{++++}$ (very severe). This method allowed qualification grading.
6. Volunteers who had exhibited some symptoms prior to the HPT (as per participant history) were dismissed. Same was true for those who exhibited same or similar symptoms as an effect of the medicine. Based on the above criteria, the MQI was 4+4+4+4 = 16.

Guidelines, Ethics, Compliance, and Approvals

The HPT project was grounded on the guidelines advocated by Samuel Hahnemann in *Organon of Medicine* [3] and the guidelines of the

CCRH (Central Council for Research in Homoeopathy, Government of India) [6] and the ECH (European Committee for Homeopathy) [7]. The project was reviewed and approved on January 16, 2012 by the Institutional Ethics Committee (Homeopathy India Pvt Ltd., Mumbai, India) and constituted as per ICMR (Indian Council of Medical Research) guidelines [8]. The requirements regarding the obligations of investigators as per 'Guidance on Good Clinical Practice' of ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Independent Ethics Committee) were met [9]. The project has been registered (no. CTRI/2012/02/002449) with the Clinical Trials Registry India (CTRI) [10] and set up by the ICMR's National Institute of Medical Statistics (NIMS).

Investigations

The evaluation of pre and post drug administration included complete blood count, erythrocyte sedimentation rate, blood biochemistry, routine urine analysis, pregnancy test, chest X-ray, and ECG. Other investigations as indicated were done at the last visit.

Inclusion, Exclusion, and Withdrawal Criteria

The volunteers (age group of 18–45 years) had to be healthy in the sense that they would not show significant psychic or physical symptoms and not consider themselves to be in need of medical treatment. The volunteers must be trustworthy and in a mental and legal state to give consent. There should be no plans for important changes in life (marriage, etc.) or for medical or surgical treatments. Further, we investigated whose ECG and X-ray reports were within normal range limits.

The exclusion criteria were no current medical treatments, intake of contraceptive pills in the last 3 months or surgical treatment within the past 2 months; further pregnancy and breast feeding should be excluded as well as diabetes, hypertension, and hypothyroid, allergic manifestations particularly pertaining to the respiratory system.

If a participant developed exclusion criteria during the study (accident or hospitalization), the data recorded until the event was considered for analysis and marked as 'withdrawal'. Those who withdrew from the study were not replaced by other participants. Those who were lost to follow-up, withdrew their consent to continue participation, and those who showed serious adverse events/symptoms were also marked as withdrawal.

Run-In Period, Dose, and Repetition

Every volunteer was given a dose of placebo, 6 pills 3 times a day, for 1 week of run-in period, and was observed for occurrence of symptoms. The symptoms experienced during the run-in period were documented carefully. Thereafter, the drug preparation (6 pills, 30c potency) was administered to every volunteer 3 times a day, for 4 subsequent weeks, unless there were severe symptoms or serious adverse events.

Pathogenetic Effects

The pathogenetic effect is defined as any change in clinical events and laboratory findings during a HPT and is recorded in the final report [4]. The overall incidence of pathogenetic effects and the incidence of pathogenetic effects per volunteer were calculated as follows:

- The overall incidence of pathogenetic effects = number of volunteers who had at least 1 pathogenetic effect / total number of volunteers taking the medicine and reporting symptoms or signs.
- The incidence of pathogenetic effects per volunteer = total number of findings claimed in the trial / total number of subjects using the medicine and included in the final pathogenetic description.

In CP-010 study, 22 volunteers were randomized in a 2:1 ratio of verum to placebo. In the verum phase, volunteers exhibited symptoms for 35 days, in the run-in period for 7 days. In the placebo phase, volunteers had symptoms for 42 days.

The investigator had conducted quantitative analysis (quantitative pathogenetic index) and qualitative analysis (qualitative pathogenetic index) considering the above variables within the 2 groups.

The quantitative pathogenetic index was calculated as follows:

Quantitative pathogenetic index = total number of findings claimed in the trial / total number of subjects using the medicine and included in its final pathogenetic description / number of days.

A = Quantitative pathogenetic index, B = total number of findings claimed in the trial, C = total number of subjects using the medicine and included in its final pathogenetic description, D = number of days.

Quantitative Pathogenetic Index (A) = (B/C)/D.

The qualitative pathogenetic index was calculated as follows:

Qualitative pathogenetic index = total number of symptoms for particular intensity / number of volunteers contributed above symptoms / number of days.

Qualitative Pathogenetic Index (A) = (B/C)/D.

Out of 15 volunteers in the study group, 14 volunteers had symptoms or signs. One volunteer had not exhibited a single sign and symptom throughout the study period. The overall incidence of pathogenetic effects is calculated as follows:

The overall incidence of pathogenetic effects = number of volunteers who had at least one reported pathogenetic effect (14) / total number of volunteers taking the medicine and who contributed symptoms or signs (14) = 14/14 = 1.

In total, there were 136 symptoms reported by 14 volunteers. The incidence of pathogenetic effects per volunteer is calculated as follows:

The incidence of pathogenetic effects of verum per volunteer = total number of findings claimed in the trial (136) / total number of subjects using the medicine and included in the final pathogenetic description (14) = 136/14 = 9.714.

Similarly, the incidence of pathogenetic effects of placebo per volunteer is calculated as symptoms (30) / number of volunteers (7) = 30/7 = 4.286.

The pathogenetic effect of the verum and placebo per volunteer per day was calculated by dividing the pathogenetic effect per volunteer by the number of daily doses: verum group: 9.714/35 = 0.278; placebo group: 4.286/42 = 0.102.

Results

HPT Symptoms

From the day of their appearance till the end of week 5, the symptoms, their intensity, and duration have been listed for all volunteers in the verum group (n = 15) (figs. 2 and 3; for detailed presentation of results see table 1 and 2 available at *www.karger.com/doi/10.1159/000365116)*.

Incidence of Pathogenetic Effects, Quantitative Pathogenetic Index, and Qualitative Pathogenetic Index

Participants in the verum group (n = 15) showed 136 symptoms in 5 weeks; those in the placebo group (n = 7) had 30 symptoms in 6 weeks. In the run-in period, 15 out of 22 participants showed 40 symptoms. The incidence of pathogenetic effects per volunteer in verum (IP) group is 9.714 versus 4.286 in the placebo group; and the pathogenetic effect per volunteer per day is 0.278 (verum group) and 0.102 (placebo group), which is significant.

It must be noted that symptoms with description of location, sensation, modality, duration, and intensity have been listed as sub-symptoms. The volunteers (with prior training), the coordinator, and the principal investigator carefully noted and verified the intensity of each symptom in detail. The strik-

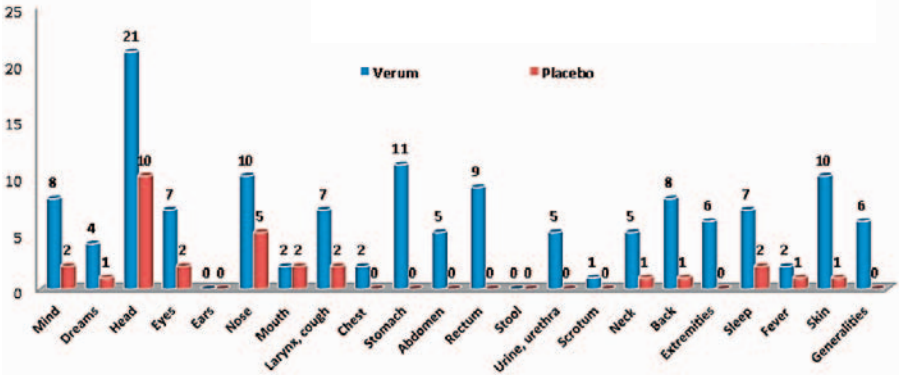

Fig. 2. Number of symptoms: verum versus placebo.

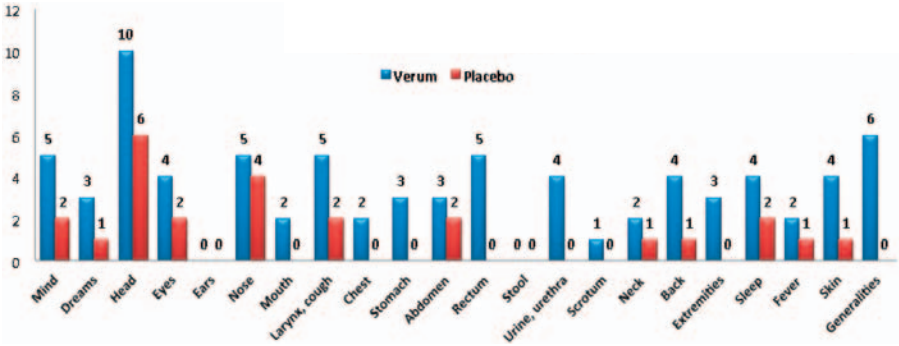

Fig. 3. Number of volunteers: verum versus placebo.

ing outcome is 136 symptoms produced by verum, which is qualitatively as well as quantitatively higher than symptoms that occurred in the control group.

Deviations in Laboratory Reports

One volunteer showed an increase in total leukocyte count from 5,600 to 11,500 (randomization no 002). On the other hand, we found a decrease in white blood cells count from 11,700 to 7,200 (volunteer randomization no 007) and from 11,800 to 8,100 (volunteer randomization no 018); the same applies for eosinophil that decreased from 10 to 7 (volunteer randomization no 008). There were no clinically significant changes after the HPT, with respect to liver function tests, renal function tests, urine analysis, and ECG. All pre- and post-investigation reports were documented.

Safety Reports

Safety of volunteers was evaluated based on pre-investigation at screening and post drug administration investigations. There were no adverse events reported during the study period.

Prominent and Clinically Applicable Symptoms

Prominent and clinically applicable symptoms have been listed as follows:

- Mind (n = 5; 1^{++}, 2^{++}, 6^{+}, 9^{++}, 20^{+}). Irritable, depressed and stressful, lethargic, desire to be alone, nervous, anxious. Upset (less with music). Anxiety, anticipation, in the morning; not fresh, dreams (old friends, school, visiting religious place, accident).
- Pain: 51 symptoms out of 106 are related to some kind of pain (head, eyes, chest, neck, back, joints, body, etc.). Burning, aching, throbbing, pulsating pain. Burning was found in mouth, stomach, abdomen, urethra, eyes, and skin.
- Headache (n = 10; 2^{+++}, 3^{+++}, 4^{++}, $6^{++,}$ 8^{++}, 9^{+}, 12^{+}, 13^{+}, 19^{++}, 20^{++}). Pain in head, forehead, and occiput. Aching, throbbing, pulsating pain, morning, forenoon, afternoon.
- Eye (n = 4; 1^{+}, 4^{+}, 6^{++}, 9^{++}). Burning (n = 2; 4^{+}, 6^{++}), photophobia (n = 2; 1^{+}, 4^{+}), irritation, redness, dryness, and lachrymation.
- Nose, coryza with watery discharge (n = 5; 1^{++}, 4^{+++}, 6^{+++}, 8^{++}, 12^{+}). Watering from nose < 7–9 a.m. (n = 2; 6^{+++}, 8^{++}). Sneezing.
- Larynx, cough, expectoration (n = 5; 1^{++}, 2^{++}, 4^{+}, 15^{+}, 20^{+}). Irritation, dryness, dry cough (n = 4; 1^{++}, 2^{++}, 4^{+}, 15^{+}). Expectoration, white, yellow.
- Mouth (n = 2; 1^{++}, 14^{++}). Ulcer, dryness, burning.
- Stomach (n = 4; 1^{++}, 6^{+}, 15^{+}, 20^{++}). Stomach, appetite increased (n = 3; 1^{++}, 6^{+}, 15^{+}). Weight gain. Burning in epigastrium after food intake; fullness, increased thirst (for cold water), craving for non-vegetarian food, chicken, meat.
- Abdomen (n = 2; 3^{++}, 4^{+}). Fullness, distension, burning, pulling pain after food intake, lying, lying on abdomen, bending.

– Rectum (n = 5; 1^{++}, 2^{++}, 3^{+++}, 4^{+++}, 8^{+++}). Diarrhea (watery stool), with thirst for large quantity of water. Constipation with hard stool, straining, flatus.
– Urethra, urine (n = 4; 1^{++}, 4^{+++}, 6^{++}, 22^{+}). Frequent urination, profuse, yellow; burning micturition.
– Neck (n = 2; 4^{+}, 9^{++}) and back (n = 4; 4^{+}, 6^{++}, 8^{++}, 22^{++}). Neck pain, aching, soreness; back pain at night; lumbosacral aching in the morning (getting up) and afternoon (resting); neck pain goes along with back pain and back pain with pain in extremities (n = 3; 4^{++++}, $6^{++,}$ 20^{++}). Pain in thighs, knees, legs, calves, soles (less in the morning).
– Sleep (n = 4; 4^{++}, 6^{+++}, 9^{++}, 19^{++}). Sleepiness, sleeplessness.
– Fever (n = 2; 12^{++}, 14^{++}). Fever with body aching and chill.
– Skin (n = 4; 1^{++}, 6^{++}, 8^{++}, 20^{++++}). Eruption, red, papular, with itching (increasing in the evening, at night, and while undressing). Painful hard boils with itching and pain; boils on scrotum. Itching on chest, neck, forearm, arm, upper limbs, thigh, neck, popliteal fossae, scrotum, all over body; with or without eruptions.
– Generalities (n = 6; 1^{++}, 4^{+}, 6^{+}, 12^{++}, 19^{++}, 20^{++}). Feeling cold, chill. Body ache (increasing at night). Weakness, fatigue, increased appetite and weight; perspiration in palms and soles; craving for meat, chicken.

Discussion

The careful appraisal of symptoms produced during verum, placebo, and run-in period was carried out by applying 4 filters to determine the prominence of symptoms: a) symptoms observed in more than 1 volunteer; b) symptoms that lasted for a significant period; c) very intense symptoms, without the volunteer having experienced such in the past 1 year and without any apparent (causal) reason; d) symptoms should finally be compared with the symptoms based on the known effects of capsaicin alkaloids, which is adequately established.

Capsaicin and dihydrocapsaicin (capshydro) are known to produce symptoms, such as itching, burning-stinging pain on skin, eyes, mouth and stomach; pain, inflammation, cough and irritation of mucous membrane; intense tearing pain in eyes conjunctiva (and blepharospasm); nausea, vomiting, abdominal pain and burning diarrhea; cough, irritation in throat, breathlessness [11]. Interestingly enough, the homeopathic pathogenetic trial reflected most of these symptoms. It is interesting to see, how such a small dose can influence the human system – also proclaiming the evidence of effect, which is controversially discussed. The fundamental homeopathic principle 'similia similibus curenture' provides that any substance which can produce a totality of symptoms in a healthy human being can in turn cure that totality of symptoms in a sick human being [12]. Based on this observation, the potentized capshydro should have a capacity to treat and relieve symptoms, such as pain, itching, inflammation, cough or the like. The aim of this study was to prepare the base for therapeutic application of oral medicine for painful conditions, sourced from the introduced alkaloids.

In our study, 53 (39%) out of 136 symptoms (head (21), eyes (5), mouth (1), chest (1), stomach (2), abdomen (4), neck (5), back (9), extremities (5)) are related to some kind of pain, which is outstandingly suggestive of scope for this remedy in wide range of acute, sub-acute, and chronic painful conditions. 10 out of 15 volunteers suffered from headache on many days, with significant duration and intensity, reflecting the pain-producing (hence pain-relieving) capacity of this preparation.

Similarly, careful examination of the data shows heavy symptomatology of acute upper and/or lower respiratory catarrh, nasal congestion, coryza, sneezing, cough, laryngeal irritation, headache, burning and aching eyes, chest congestion and pain, chill with fever, body ache, and joint pain. These findings point toward the role of medication in acute upper and lower respiratory infections. Reduction in leukocytes (11,800 to 8,100) and eosinophils (10 to 7) may be incidental and therapeutically not relevant, but certainly noteworthy (see section on 'deviations in laboratory reports'). Gastrointestinal symptoms were notable as the medication produced relevant symptoms in mouth, stomach, intestines, and rectum. Certain symptoms, such as craving for meat (chicken), increase and decrease in appetite as well as thirst, perspiration in palms and soles, and chill were observed. Oral and gastrointestinal exposure to capsaicin increases satiety and reduces energy as well as fat intake [13]. In turn, capsaicin has an effect on weight loss and regain. Interestingly, 1 volunteer developed increased appetite and gained 2 kg of weight in 2 weeks. This observation calls for further exploration. At the level of mind, anxiety, irritability, depression, desire to be alone, etc. were observed in 5 volunteers.

Interestingly, ultra-high diluted (30c potency) capsaicin and dihydrocapsaicin produced substantial symptoms, which is undoubtedly comparable with the toxicological effect of the crude substances. Thus it can be concluded that potentized preparation has action on human system, and the action is comparable with the effect of the crude substance.

The symptoms produced by the verum have shown to be evidently more significant, quantitatively in terms of the incidence of pathogenetic effects in verum group of 9.714 as compared to 4.286 in the placebo group. The author has introduced a similar quantitative symptom index, which in verum group is 0.278 as compared to 0.102 in the placebo group. However, it may be noted that if 1 or more volunteers in the placebo group were highly sensitive, the study may be biased. In other words, difference in the index may serve as an indicator of quality but does not need to be rated as mandatory. Since we have eliminated similar symptoms produced during the run-in phase compared to the verum phase in the same volunteers, the qualitative symptom index in run-in period does not remain comparable with that of the verum phase.

Conclusion

We conducted a double-blind, randomized placebo-controlled HPT with capsaicin and dihydrocapsaicin, administered orally in potentized form (30c potency) as a new medicine in homeopathy. The study included 15 volunteers and 7 controls, with 7 days of run-in period. The application of verum led to 136 symptoms, which is quantitatively and qualitatively more than in the control group. These symptoms were comparable with toxicological symptoms; safety of healthy volunteers was documented, and thus clinically usable data was generated.

The HPT revealed clear symptomatology, which can easily be reproduced in clinical practice for conditions presenting with pain and inflammation in particular, affecting any system in the body. The experiment influenced upper and lower respiratory tracts, skin, joints, and muscles as well as gastrointestinal and urinary tract.

Further research along similar lines may help introducing more homeopathic medication to medical practice, filling the gap between homeopathy and conventional medicine. Further clinical trials could enhance the strength of the current experiment and its outcome.

Acknowledgments

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Disclosure Statement

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