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HIV Nosode: The Homeopathic Pathogenetic Trial

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Keywords
HIV · Nosode · Homeopathic pathogenetic trial · Drug proving · Double blind · Randomization · Placebo control · Ethics · Quantitative pathogenetic index · Qualitative pathogenetic index · Symptoms

Summary
Background: Deriving clinical indications for the HIV nosode by conducting a double-blind, placebo-controlled homeopathic pathogenetic trial (HPT) with the aim to introduce a new nosode to the profession. **Method:** The HPT was conducted in 22 volunteers, 15 of which received HIV nosode in 30c potency pills, while 7 received identical placebo pills orally, once a week, for 4 weeks. The volunteers' symptoms during initial 7 days of run-in period were noted. All symptoms for both groups produced during run-in period were excluded from final analysis. Informed consent form, approval by Ethics Committee, laboratory investigations as well as safety and ethical measures were provided. The volunteers were trained to write data in prescribed diaries, and the data were analyzed. **Results:** The HPT of the HIV nosode exhibited qualitatively distinct symptoms, which can be applied in clinical practice. Number of symptoms reported in verum group was 130, in placebo group 60. Quantitative pathogenetic index was 0.285 in verum group, 0.238 in placebo group; qualitative pathogenetic index was 0.1402 in the verum group as compared to placebo (0.0907). Safe use was documented. **Conclusion:** This study brought in guiding symptoms, which will help the profession to employ this nosode in practice.

Schlüsselwörter
HIV · Nosode · Homöopathische pathogenetische Studie · Arzneimittelprüfung · Doppelblind · Randomisierung · Placebo-Kontrolle · Ethik · Quantitativer pathogenetischer Index · Qualitativer pathogenetischer Index · Symptome

Zusammenfassung
Hintergrund: Ermittlung klinischer Indikationen zur HIV-Nosode mittels einer doppelblinden, Placebo-kontrollierten homöopathischen pathogenetische Studie (HPS) mit dem Ziel, eine neue Nosode zu entwickeln. **Methodik:** Die HPS wurde an 22 Freiwilligen durchgeführt, von denen 15 eine HIV-Nosode in Form von 30c-potenzierten Tabletten erhielten, während 7 Teilnehmer 4 Wochen lang einmal wöchentlich ein entsprechendes Placebo verabreicht bekamen. Die Symptome während der Run-in-Periode wurden in den ersten 7 Tagen erfasst. Alle Symptome, die in dieser Zeit in beiden Gruppen beobachtet werden konnten, wurden von der Analyse ausgeschlossen. Eine Einverständniserklärung, die Erlaubnis einer Ethikkommission, Laboruntersuchungen und Sicherheits- sowie ethische Maßnahmen lagen vor bzw. wurden durchgeführt. Die Probanden wurden in der Dokumentation der Ergebnisse in dafür vorgesehene Tagebücher angeleitet; im Anschluss wurden die Daten ausgewertet. **Ergebnisse:** Die HPS der HIV-Nosode brachte qualitativ unterschiedliche Symptome hervor, was in der klinischen Praxis Verwendung finden kann. Die Anzahl der Symptome in der Verum-Gruppe betrug 130, in der Placebo-Gruppe 60. Der quantitative pathogenetische Index betrug in der Verum-Gruppe 0,285 und in der Placebo-Gruppe 0,238. Der qualitative pathogenetische Index betrug 0,1402 in der Verum-Gruppe, im Vergleich zu Placebo (0,0907). Die Anwendung wurde als sicher evaluiert. **Schlussfolgerung:** Die Studie brachte Leitsymptome hervor, die nützlich sein können, die Nosode in der Praxis einzusetzen.

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Introduction

Nosodes, the homeopathically potentized preparations from microbes, secretions, discharges or tissues, have been in use since 1833 [1]. The homeopathic profession has eagerly awaited the HIV nosode ever since the discovery of the Human Immunodeficiency Virus by Robert Gallo and Luc Montagnier [2] in 1984.

The potentized homeopathic medicines are administered in 30c, 200c (or higher) potencies. Nosodes are known to impact the deep miasmatic state of patients. The HIV nosode has a potential as a broad-spectrum remedy in a range of diseases. The author identified the scope for upgrading the current method of preparation. The method of HIV nosode preparation was designed, facilitated, and approved with the support of a team comprising virologists, immunologists, biotechnologists, legal attorneys, homeopaths, pharmacologists, microbiologists, social workers, and conventional HIV physicians.

It may be noted that Norland made a good attempt at preparing AIDS nosode [3], from blood sample of a patient suffering from HIV, without any standardization; and it was not a controlled study.

Brief Note about the Preparation of HIV Nosode

The HIV nosode preparation was done as per an elaborate 15-step method [4] after approval for the project from the Institutional Ethics Committee (IEC). The method comprised mixing of sera containing HIV type I and II from 2 Indian male patients with HIV type I and II infection, respectively, in equal quantity before undertaking potentization; screening of samples for the presence of possible co-infections (Hep C, Hep B, Gonorrhea, Syphilis); expression of serum; filtration for large particles and bacteria; standardization in terms of viral load by RT-PCR method; documentation of viral load; use of water for injection as a vehicle; documentation of force parameters for potentization (electro-mechanical device, calculation of impact of stroke); and preparing HIV nosode 30c potency, as per the Hahnemannian multi-vial dilution method. The safety of the use of the HIV nosode 30c potency in human beings was established by checking the nosode for the presence of HIV type I and II, by RT-PCR method, pro-viral DNA test, and ultra-electromicroscopy [5]. The investigations were carried out at accredited laboratories.

Method

The homeopathic pathogenetic trial (HPT) of the HIV nosode was conducted through double-blind, randomized, placebo-controlled study at the Life Force Center in Mumbai, India, from June to August 2011. The drug was proved in 30c potency on 22 volunteers (3 females, 19 males), after obtaining their informed consent, with randomization ratio as 2:1 [6]. 15 volunteers were given the verum and 7 were given matching placebo.

The preparation was administered in 30c potency: one dose administered in the morning, once a week for 4 weeks. In case of very severe symptoms, further application should be withheld and a suitable antidote should be administered as indicated. The preparation was administered with 6 globules of 30 size, to be taken orally and allowed to get dissolved, avoiding any food intake for at least 20 min before and after the dose. The placebo pills were of identical size.

The volunteers were selected based on the inclusion and exclusion criteria as per protocol. The volunteers had mean age of 26.6 years, from various walks of life; different geographical locations, socio-economic status, and occupations, including students and homeopaths. The volunteers underwent prescribed investigations. Current and past clinical histories of volunteers were recorded in detail. Each volunteer had completed intake of one placebo dose on the first day with 7 days of run-in period, followed by one dose of medicine weekly, for the next 4 weeks. The pathogenetic index (PI) physicians and the study physicians consulted the volunteers during every visit. The symptoms appearing during the trial period (up to 6 weeks) were noted in a diary provided to the patients that was cross-examined and elaborated by the principal investigator (PI).

Guidelines, Ethics, Compliance, and Approvals

The HPT project is based on the guidelines advocated by Samuel Hahnemann [7], the Central Council for Research in Homoeopathy, Government of India (CCRH) [8, 9], and European Committee for Homeopathy (ECH) [10]. The project was approved on June 12, 2011 by the Homeopathy India Pvt Ltd, Mumbai (IEC) and constituted as per the Indian Council of Medical Research (ICMR) guidelines [11]. The guidelines for 'Good Clinical Practice, constituted by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Independent Ethics Committee (ICH) [12], were met. The HPT project was registered (no. CTRI/2011/12/002265) in Clinical Trials Registry, India (CTRI) [13] and set up by the ICMR's National Institute of Medical Statistics (NIMS). Manuscript writing and data reporting have been done according to CONSORT (RedHot) guidelines [14].

Investigations

Pre- and post-drug administration investigations included complete blood count, Erythrocyte Sedimentation Rate (ESR), HIV screening (HIV-DUO (serum) by CMIA IV Generation test), blood biochemistry, urine routine analysis, pregnancy test, chest X-ray, and electrocardiogram (ECG).

Inclusion Criteria

The volunteers had to be healthy, trustworthy, have no plans to begin medical or surgical treatments, without significant psychic or physical symptoms, and must be mentally and legally competent to exercise their choice and to give informed written consent.

Exclusion Criteria

Volunteers being currently in treatment, using contraceptive pills in the preceding 3 months, having undergone surgical treatment within the past 2 months, being pregnant, breastfeeding, suffering from any allergy, having diabetes, hypertension, hypothyroidism, and drug addicts or those HIV-infected were excluded from the trial.

Withdrawal Criteria

Participants having severe adverse events like accidents or hospitalization were considered for analysis and marked as 'withdrawal', without being replaced.

Run-in Period, Dose, and Repetition

Every volunteer was given a dose of placebo on day one, and was observed for 7 days. The first week was defined as run-in period. The symptoms experienced during the run-in period were documented carefully. One dose of 30c potency was administered to every volunteer, once a week, for 4 consecutive weeks, unless there were severe symptoms or serious adverse events (SAE) (fig. 1).

Pathogenetic Effect of HIV Nosode

The overall incidence of pathogenetic effects was calculated as follows:

The incidence of pathogenetic effects = number of volunteers who had at least one reported pathogenetic effect (13) / total number of volunteers taking the medicine and who showed symptoms or signs (14) = 0.928.

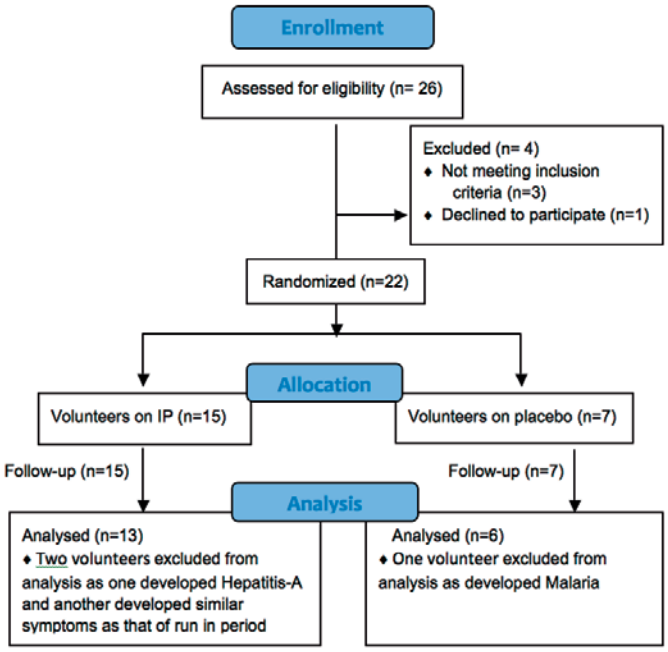

Fig. 1. Flow chart of screening, recruitment, randomization, and study completion.

The pathogenetic effect is defined as any change in clinical events and laboratory findings reported by volunteers during the HPT and recorded in the final report. In this study, all 15 volunteers showed symptoms. However, since one developed Hepatitis A and another continued producing symptoms similar to those occurred in the run-in period, these symptoms were not included in the final report which contained 13 volunteers experiencing a pathogenetic effect. The total number of symptoms reported by the 13 volunteers was 130 (the incidence of pathogenetic effects per volunteer = total number of findings claimed in the trial (130) / total number of subjects using the medicine and included in the final pathogenetic description (13) = 10).

Other Indices Analyzed

Some researchers have suggested examining HPT data in terms of pathogenetic effects [15]. Based on the experience with the HPT with 4 new medicines [4, 16], the PI was introduced as further evaluation tool (quantitative/qualitative pathogenetic indices [16]) to compare the results of HPT in verum and placebo groups:

1. Quantitative PI = total number of symptoms claimed in the trial / number of days × total number of subjects)

2. Qualitative PI = total number of symptoms for particular intensity / number of volunteers showing symptoms × number of days

Methodological Quality Index (MQI)

The MQI is based on key components of methodological quality including internal and external validity items. The MQI 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. *Randomization:* Pre- generated random number table randomization kits were allocated to volunteers on first-come-first-served basis, using sequentially numbered opaque sealed envelopes (SNOSE) scheme [17, 18]. Kits were coded with randomization numbers, prepared by an independent person who was unaware of the trial procedures.

Blinding (double-blind): The medicine was coded for the HPT purpose and the volunteers, coordinators, and the PI physicians were blinded to treatment allocation. The blinding for randomization was maintained until the completion of the trial and data entry and then unfolded for comparison of symptoms in both treatment groups.

Inclusion and exclusion criteria: Symptoms of any intensity emerging after the intake of the IP were included in the analysis. Any symptom, even if not intense but found in more than two volunteers, was considered significant for analysis. Symptoms experienced for longer duration and/or occurring more frequently than two were graded as intense.

Criteria for Selection of Effects

1. Symptoms that occurred during the run-in period (first week, with placebo) and in volunteers who dropped out from the study due to adverse events were excluded. Symptoms that were observed in the placebo and verum group were analyzed quantitatively as well as qualitatively.

2. Symptoms that occurred in both groups were evaluated on the basis of intensity and duration, e.g., headache in the placebo group reported as mild ($^{+}$), while reported as severe ($^{+++}$) in the verum group, was not eliminated.

3. Symptoms were reported quantitatively (daily) with duration and frequency, e.g., dull headache with a feeling of heaviness all over the head <3 h associated with sleepiness (n = 1) (9^{+} (day 22 for 2–3 h)).

4. Symptoms described by the volunteers have been graded as $^{+}$ (mild), $^{++}$ (moderate), $^{+++}$ (severe), and $^{++++}$ (very severe). This method allowed qualitative grading.

5. Volunteers who had exhibited certain symptoms prior to the HPT (as per history) were excluded, if same or similar symptoms occurred after medicine intake.

Statistical Analysis

We conducted a t-test for verum and placebo group with equal variance and found a significant difference between the both groups (p value = 0.002). The intensity of the symptoms in the verum group was statistically significant as compared to placebo.

Results

The HIV nosode was prepared using a standardized, updated, reproducible method. A double-blind, randomized, placebo-controlled HPT of the HIV nosode exhibited qualitatively distinct symptoms, which can be applied in clinical practice. The HIV nosode intake proved to be safe for volunteers.

The results were evaluated in 3 parts: a) Complete list of symptoms experienced by the volunteers; b) HIV nosode HPT versus HIV/AIDS disease symptoms; c) Selected HIV nosode symptom for clinical practice.

HIV Nosode Pathogenetic Trial Symptoms

A) All symptoms that occurred during run-in period (first week, with placebo) as well as with verum (n = 15).

B) Symptoms that occurred during the verum phase for 4 weeks (n = 15). Those identical symptoms proved during run-in period *as well as* in the verum phase, were not included in the category b, avoiding known placebo induced symptoms.

C) Symptoms produced by placebo group (7 volunteers), for five weeks (n = 7).

Following are the symptoms from category b (verified against groups a and c), produced under the effect of the verum.

In the first parenthesis, the number indicates the number of volunteers (n) with a particular symptom, while in the second parenthesis, the number indicates volunteer's randomization number and the intensity of the symptom.

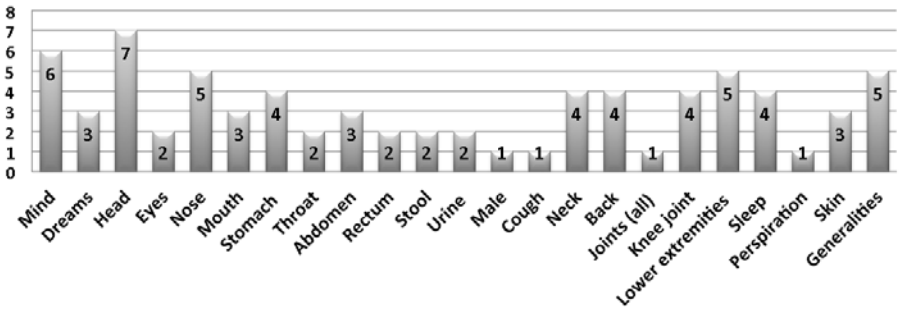

Fig. 2. Anatomical location of symptoms and number of volunteers.

Mind: Anger (n = 1) (2^{++}), confusion of mind (n = 1) (21^{++}), depression (n = 1) (1^{++}), dual thoughts (n = 1) (21^{++}), disturbed feeling (n = 1) (10^{++}), hurriedness (n = 1) (21^{++}), irritability (n = 5) (1^{++}, 2^{++}, 4^{+}, 14^{+}, 21^{+++}), feeling of loneliness (n = 1) (1^{+}), restlessness (n = 1) (21^{+++}), frustration (n = 1) (2^{++}), weeping (n = 1) (14^{+}).

Dreams: Dreams about snatching ones gadget (n = 1) (21^{++++}), Dreams about death (n = 1) (10^{++}), dreams about heading somewhere, without reaching the destination / feeling lost (n = 1) (1^{+}), dreams about travelling (n = 1) (1^{+}), dreams of accident and blood (n = 1) (1^{+}).

Head: Dull headache (n = 3) (5^{+++}, 9^{+}, 10^{++}), headache frontal (n = 1) (18^{++}), pricking headache (n = 1) (7^{+++}), heaviness of head (n = 2) (1^{+}, 6^{+}), bursting headache (n = 1) (5^{+++}), pulsating pain in temporal region with redness of eyes (n = 1) (5^{+++}).

Eyes: Burning, heaviness, irritation in eyes, blurred vision with lacrimation (n = 1) (21^{++++}), pain in the eye (n = 1) (5^{+}).

Nose: Watery discharge (n = 3) (6^{+}, 9^{+}, 21^{++++}), running nose alternate with blocked nose (n = 1) (9^{+}), sneezing (n = 2) (6^{+}, 18^{++}), watery coryza, with sneezing and feverish feeling (N = 1) (12^{+}).

Throat: Pain (n = 2) (2^{++}, 21^{++++}), difficult expectoration (n = 2) (2^{++}, 21^{++++}), irritation and pulling sensation (n = 1) (21^{+++}).

Mouth: Mouth ulcers (n = 2) (14^{++++}, 21^{++}), inflamed upper palate (n = 1) (21^{++}), bleeding gum for 4 days while brushing teeth (n = 1) (18^{++}).

Stomach: Reduced appetite (n = 2) (1^{+}, 12^{++}), sour stomach eructation (n = 1) (21^{+++}), retrosternal burning (n = 1) (10^{++}), increased thirst with bitter taste in mouth (n = 1) (21^{+++}), ravenous appetite (n = 1) (21^{++++}), feeling hungry, yet nausea and vomiting (n = 1) (5^{++}).

Abdomen: Pain (n = 3) (1^{+}, 14^{+}, 21^{++++}), overacidification and burning in epigastric region (n = 1) (1^{+}).

Rectum: Burning in anus (n = 1) (2^{++}), itching around anus (n = 1) (21^{++}).

Stool: Constant need to pass stools (n = 1) (21^{++++}), fecal incontinence (n = 2) (14^{+}, 21^{++++}).

Urinary organs: Sharp pain when urinating (n = 2) (5^{+}, 21^{+++}), bladder weakness (n = 1) (21^{++}).

Male sexual organs: Premature ejaculation (n = 1) (17^{+}).

Cough: Dry cough (n = 1) (4^{++}).

Neck: Twitching of shoulder muscles (n = 1) (21^{+++}), pain (n = 3) (1^{+}, 10^{++}, 17^{+++}).

Back: Pain (n = 4) (1^{+}, 14^{++}, 18^{+++}, 21^{+++}).

Extremities: Pain in knee joint (n = 2) (1^{+}, 21^{+++}), pain in soles (n = 2) (14^{++}, 21^{++}), pain in leg (n = 3) (1^{+}, 2^{++}, 21^{++++}), pain in all joints (n = 1) (21^{++++}).*Fever:* Fever with chills (n = 2) (5^{+++}, 21^{+}), feeling feverish (n = 1) (1^{+}).

Sleep: Sleepiness (n = 2) (14^{++}, 21^{+++}), feeling drowsy (n = 2) (1^{+}, 21^{+++}), sleeplessness (n = 1) (6^{+}), disturbed sleep (n = 1) (1^{+}), unrelaxing sleep (n = 1) (1^{+}).

Perspiration: Perspiration all over body (n = 1) (7^{+}).

Skin: Acne over right cheek (n = 1) (21^{+++}), papular eruption (n = 2) (1^{++}, 14^{++}), itching (n = 2) (1^{+}, 21^{+++}).

Generalities: Exhaustion and tiredness (n = 3) (1^{+}, 2^{++}, 21^{+++}), body ache (n = 4) (5^{++}, 7^{++}, 10^{++}, 21^{+++}), lethargic feeling (n = 1) (1^{+}), weakness (n = 2) (2^{++}, 12^{++++}), increased sensitivity to heat (n = 1) (1^{+}).

Data Evaluation Indices

There was a marked difference in the qualitative pathogenetic index between the verum and the placebo group with a statistically significant difference (p value = 0.002) in mild intensity ($^{+}$) in the verum phase (0.137) as compared to the placebo (0.052) group. For verum, strong intensity ($^{+++}$) was at 0.131, as compared to placebo with 0.107; very strong intensity ($^{++++}$) was at 0.171 for verum, as compared to placebo at 0.071. On average the qualitative pathogenic index was at 0.1405 for verum and 0.0907 for placebo.

Figure 2 represents the symptoms in their anatomical location and the number of volunteers. Figure 3 shows the qualitative symptom study, while figure 4 displays organ-related symptoms of IP versus placebo.

The volunteers (N = 13) exhibited symptoms the following areas: mind (6), dreams (3), head (7), eyes (2), nose (5), mouth (3), stomach (4), throat (2), abdomen (3), rectum (2), stool (2), urine (2), cough (1), neck (4), back (4), joints (1), knee joint (4), lower extremities (5), sleep (4), perspiration (1), skin (3), general (5).

The incidence of pathogenetic effects in the verum and placebo group was identical (10). The PI was introduced as another index to measure the pathogenetic effect (QPI). As a result, the verum group was at QPI = 0.285 and the placebo group at QPI = 0.238, showing a significant difference. In this regard, the run-in period index is not comparable as the run-in period symptoms have been eliminated from the IP group. Therefore, another dimension of QPI was added, by incorporating the intensity of each symptom ($^{+, ++, +++, ++++}$) in each group (verum = 0.1402; placebo = 0.0907). The results were also significant.

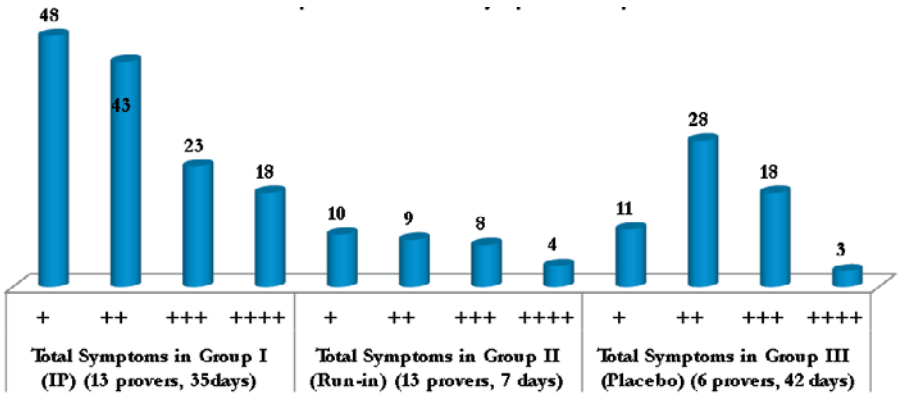

Fig. 3. Qualitative symptom study.

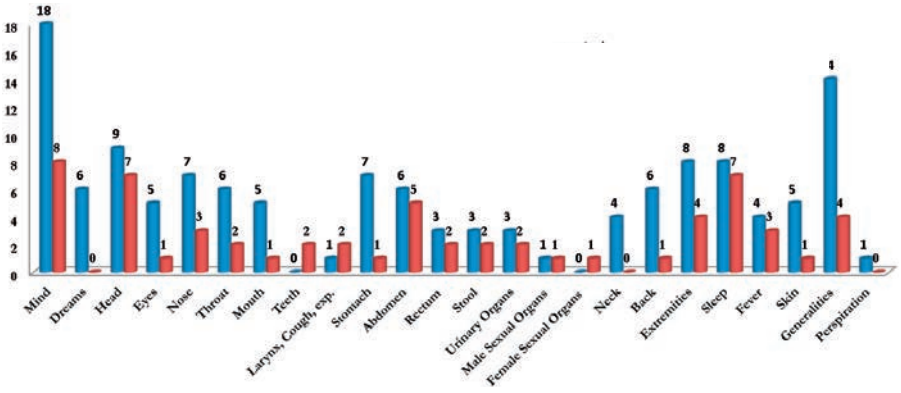

Fig. 4. Organ-related symptoms of pathogenetic index (PI) versus placebo.

Deviations in Lab Reports

There were no significant changes after the HPT, in complete blood count, liver function tests, renal function tests, urine analysis, and ECG.

Adverse Events and Exclusion of Volunteers

Two volunteers, who developed adverse events not related to the intake of the nosode, were excluded from the HPT as they developed Hepatitis A and Malaria (confirmed with blood test), respectively; their symptoms were not analyzed. No volunteer reported SAE or serious adverse drug reactions.

Post-HPT HIV Infection Status

None of the volunteers who consumed HIV nosode in 30c potency turned HIV seropositive 6 weeks after the HPT.

HPT Symptoms versus HIV Disease Symptoms

It was observed that some of the symptoms induced by the HIV nosode corresponded with the disease. Some of these symptoms are common; each remedy also induces very specific symptoms that define its particular pattern (table 1).

Discussion

Analysis and evaluation of the HPT data is an underrated challenge, as there always remains a risk of mingling medicine effect symptoms with placebo effect symptoms. The PI indicates the importance of symptoms if observed in more than one volunteer, lasted for a significant period, without the volunteer having experienced similar symptoms in the past year and without any apparent reason for occurrence. These symptoms should finally be compared with the symptoms based on the known effect of the HIV virus. The quantitative and qualitative PI [16] offer additional tool for data evaluation in HPT. Interestingly, it was observed that the symptoms in the placebo group were qualitatively less significant than those in the verum group in terms of frequency, intensity, and duration.

It may be noted that research in HPT could not be approached with any expectation in terms of peculiar symptoms or any mental theme arising from the volunteers. This study helped to obtain pure data. Also, data pulled out from HPT is one but not the only source in Materia Medica. Study of clinical medicine data, in this case, should form the additional source of indications for HIV nosode. The HPT simulates the clinical picture of HIV, revealing effects of the virus on humans (producing much deeper pathology than the HPT), comparable with the clinical picture of tuberculosis [20] which is depicted by tuberculinum nosode [21–25].

The treatment of HIV infection needs striking guidelines for use of HIV nosode. Interestingly, HIV HPT has unveiled symptoms, which correspond with altered immune status observed in HIV-infected patients. The effect of the potentized dose of homeopathic medicine has been viewed with skepticism. This study has shown development of symptoms in healthy humans using potentized

Tab. 1. Data evaluation indices

No	Homeopathic pathogenetic trial symptoms	HIV disease symptoms
1	reduced appetite (n = 2)	reduced or loss of appetite
2	fever with chills (n = 3), body ache, tiredness, lethargy (n = 2)	flu-like symptoms (Fever, body ache, tiredness)
3	weakness, exhaustion (n = 2)	weakness, fatigue
4	body pain and joint pain(n = 2)	joint pain, muscle pain
5	throat, sore pain (n = 2)	sore throat
6	perspiration (n = 1)	perspiration, night sweats
7	nausea (n = 2)	nausea
8	skin rash (n = 3)	skin rash
9	–	weight loss
10	dry cough (n = 1)	dry cough
11	–	shortness of breath
12	fever	recurring fever or profuse night sweats
13	–	swollen lymph glands in the armpits, groin, or neck
14	diarrhea (n = 2)	diarrhea
15	ulcers in mouth (n = 2)	ulcers on the tongue, mouth, genitals
16	–	pneumonia
17	depression (n = 1), frustration (n = 1)	memory loss, depression, other neurological disorders

HIV nosode, which are intriguingly comparable with some of the symptoms in patients with HIV, which indicates that the symptom altering effects are retained in the controversial potentized form.

Conclusion

The need for a standardized and scientifically sound method for nosode preparation in light of the development of microbiology and allied streams was identified and developed. The double-blind, placebo-controlled HPT of the HIV nosode yielded clinically usable symptoms. The very nature of the process of the HPT allows mixing up drug-induced symptoms with those due to placebo effect. The support of microbe-induced disease symptoms (in case of nosodes) should be a major basis of therapeutic indications. The PI compares disease (of HIV) symptoms with those from the HPT, to support the reliability of experiment outcome. Many new nosodes can now be prepared and former nosodes can be revamped using the improved method. The study proved to be safe for healthy individuals.

The HIV nosode may find profound scope in the medical practice and needs to be reconnoitered for the treatment of immunologically mediated diseases, infections, autoimmune diseases, allergic disorders, collagen diseases, metabolic disorders, and malignancies.

Acknowledgements

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Disclosure Statement

Homeopathy India Pvt Ltd sponsored the project, yet did not have any impact on data collection, analysis, and interpretation. The author has no conflict of interests.

Supplemental Material

To access the supplemental material please refer to *www.karger.com/doi/10.1159/000435845.*

Appendix I. Blood investigations, X-ray, ECG reports, pre-post drug proving, n = 22

Appendix II. Safety report

Appendix III. Symptoms of verum group and selected symptoms for clinical practice

Appendix IV. Symptoms experienced by volunteers in the first week (run-in period) when on placebo

Appendix V. Symptoms experienced by volunteers during 5 weeks when on placebo

Appendix VI. Volunteer randomization details (A-007)

Appendix VII. Comparative analysis of symptoms in pathogenetic index (PI), placebo, and run-in phase

Appendix VIII. Qualitative study of symptoms in pathogenetic index (PI), run-in, and placebo groups

Appendix IX. Qualitative symptoms study (intensity)

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