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A multi-centric double-blind homoeopathic pathogenetic trial of *Cyclosporin*

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ABSTRACT

Objective: To elicit the pathogenetic response of the drug *Cyclosporin* in homoeopathic potencies on apparently healthy human beings.

Material and Methods: The drug *Cyclosporin* was proved by the Central Council for Research in Homoeopathy through double-blind placebo-controlled trial. The study was conducted in two centres. The drug was proved in two potencies (6C and 30C) on 50 apparently healthy volunteers who were selected after conducting pre-trial medical examinations by the medical specialists and routine laboratory investigations. In the first phase the volunteers were given 56 doses (4 doses per day for 14 days) of placebo. In the next two phases, 56 doses (4 doses per day for 14 days) of each potency or placebo were consumed. The symptoms generated during the trial period were noted by the volunteers and elaborated by the proving masters. The data obtained from the two centers were compiled at proving-cum-data processing cell at Central Council for Research in Homoeopathy (CCRH) headquarters after decoding.

Results: Out of 50 provers, 33 were on actual drug trial and 17 were on placebo. Eleven provers manifested symptoms. The drug was able to produce symptoms in each potency in most parts of the body.

Conclusion: The pathogenetic responses elicited during the proving trial expands the scope of use of the drug *Cyclosporin* and will benefit the research scholars and clinicians. These symptoms will carry more value when verified clinically.

Keywords: Cyclosporin, Drug proving, Homoeopathy, Homoeopathic Pathogenetic Trial, Immunosuppressant, Pathogenetic effect

INTRODUCTION

Cyclosporin is a medicine of conventional system. Clinical indications for *Cyclosporin* are kidney, liver, heart and other organ transplantation, rheumatoid arthritis, and psoriasis (Faulds *et al*., 1993). In psoriasis, *Cyclosporin* is indicated for treatment of adult non-immuno-compromised patients with severe and disabling disease in whom other systemic therapies have failed (Linden and Weinstein, 1999). Because of its mechanism of action, there is a theoretical basis for the use of *Cyclosporin* in a variety of other T-cell mediated diseases (Faulds *et al*., 1993). *Cyclosporin* has been reported to be effective in Behcet's acute ocular syndrome, endogenous uveitis, atopic dermatitis, inflammatory bowel disease and nephritic syndrome, when standard therapies have failed.[1]

Cyclosporin suppresses some humoral immunity but is more effective against T cell-dependent immune mechanisms such as those underlying transplant rejection and some forms of autoimmunity (Kahan, 1989). It preferentially inhibits antigen-triggered

signal transduction in T-lymphocytes, blunting the expression of many lymphokines, including interleukin (IL)-2, as well as expression of antiapototic proteins.[2] *Cyclosporin* is a second-line drug in autoimmune diseases like severe rheumatoid arthritis, uveitis, bronchial asthma, inflammatory bowel disease, dermatomyositis etc., and in psoriasis, especially to suppress acute exacerbations.[2] *Cyclosporin* A (CyA) has a selective action on the T series of lymphocytes.[3]

Keeping in view the action of *Cyclosporin* most markedly on the immune system it was felt necessary to elicit its pathogenetic effects in homoeopathic potencies. So the Central Council for Research in Homoeopathy undertook its systematic Homoeopathic Pathogenetic Trial (HPT) as per the approved protocol.

Description

Cyclosporin is a cyclic polypeptide consisting of 11 amino acids, produced as a metabolite of the fungus species *Beauveria nivea* (Borel *et al.,* 1976).[1] It was introduced as a highly selective immunosuppressant, and has markedly increased the success of organ transplants.[2] About 40% of *Cyclosporin* is absorbed from the gastrointestinal tract and is extensively metabolised in the liver, mainly by the cytochrome P450 3A system; the $t_{½}$ is 27 h.[4] Since *Cyclosporin* is lipophilic and highly hydrophobic, it must be solubilised for clinical administration.[1]

Toxicity/Adverse Reactions

The principal adverse reactions to *Cyclosporin* therapy, as per the literature reports, are renal dysfunction, tremor, hirsutism, hypertension, hyperlipidaemia and gum hyperplasia (Burke *et al*., 1994). Nephrotoxicity is limiting and occurs in the majority of patients treated. Hypertension may occur in approximately 50% of renal transplant and almost all cardiac transplant patients.[1]

Cyclosporin constricts the pre-glomerular afferent arterioles and reduces glomerular filtration; acute or chronic renal impairment may develop if the plasma concentration consistently exceeds 250 mg/l. Other adverse effects include gastrointestinal reactions, hepatotoxicity, hyperkalaemia, hypertrichosis, gingival hypertrophy and convulsions. The clinical syndrome of thrombotic thrombocytopenic purpura may follow *Cyclosporin* therapy.[3]

Potencies Used

6C and 30C.

Objective

To elicit the pathogenetic response of the drug *Cyclosporin* on apparently healthy human volunteers in homoeopathic potencies.

MATERIALS AND METHODS

Study Design

The study was a randomized, double-blind, placebo-controlled trial.

Participants and Setting

The proving was conducted at two centers: Central Research Institute, Noida during 2009-10 and Drug Proving Unit, Bhubaneswar during 2008-09. Totally 50 apparently healthy volunteers from the above mentioned two centres total 33 apparently healthy volunteers from above mentioned two centers of age group between 19 and 29 years, comprising 12 males and 38 females were enrolled. Two provers dropped out at Bhubaneswar centre.

Drug (Intervention)

Cyclosporin was procured in 6C and 30C potencies from M/s HAPCO Pharmaceuticals, Kolkata, India, a Good Manufacturing Practice compliant firm. Globules (size 30) were medicated with these attenuations at the Council's headquarters and sent to drug proving research units in coded phials (verum), along with placebo (control).

Placebo

Placebo was made up of plain globules (size 30) moistened with plain dispensing alcohol (unsuccussed), and was therefore indistinguishable from verum.

Methodology of Proving

Before commencing the study, all provers were screened strictly by the experts, and apparently healthy provers of age between 18 and 45 years, consisting of both males and females, were included in the drug proving trial. Pregnant and lactating mothers were excluded. 'Written informed consent' was obtained from each volunteer before starting the proving. Pre-trial Medical Examinations (PME) and Terminal Medical Examinations (TME) of the volunteers were carried out by General Physicians, Psychiatrists, Cardiologists, Ophthalmologists, ENT specialists, Dermatologists, Gynaecologists and Radiologists and their routine laboratory investigations were done at the centers to ascertain their health status. After the recommendation of

experts, healthy volunteers were enrolled in the Homoeopathic Drug Proving Programme. The study was conducted at the two centres mentioned above. According to Central Council for Research in Homoeopathy (CCRH) Drug Proving Protocol, the sample size included 30% volunteers under the control group at each centre.

Out of the total 50 volunteers, 33 were kept on the drug (verum) and 17 on placebo (control) in all three phases. All the volunteers were assigned code numbers, and the coded drugs of different potencies (including placebo) were supplied in separate glass phials labelled with code numbers of the respective volunteers, keeping both provers and proving masters blind about what provers were consuming (drug or placebo).

The study consisted of three phases. Each phase consisted of 56 doses of coded drugs or placebo.

Phase 1: Placebo phase. It is useful in generating prover's response to placebo, and therefore, symptoms generated by the provers in this stage act as control for subsequent phases.

Phase 2: In the second phase, the proving was conducted with 6C potency.

Phase 3: In the third phase, the proving was conducted with 30C potency.

The volunteers were instructed to take four to six globules of a particular potency of the coded drug, four times a day, dry on the tongue and were also instructed to note down the details of their feelings/changes in mind and body after taking the coded drug in "prover's day book proforma" daily.

- If no sign(s)/symptom(s) appeared

If no sign/symptom was observed, the volunteer noted down as "no symptom" with the date and time of intake of the respective dose of the drug/placebo.

- If sign(s)/symptom(s) appeared

The volunteers were asked to stop the drug/placebo as soon as he/she felt any change or any sign(s) and/or symptom(s) developed during the trial. The volunteer noted down the sequence of the appearance of new sign(s) and/or symptom(s), their progress and the number of doses after which each sign or symptom appeared, with the date, time of onset and duration for which it persisted. The intake of drug remained suspended till the sign(s) and/or symptom(s) totally disappeared. Any change in the normal routine of the prover with respect to the daily habits pertaining to diet, living conditions, etc., or any treatment taken was also noted in the "prover's day book proforma."

After the disappearance of sign(s) and/or symptom(s) developed by the drug, the volunteer had to wait for a further period of 7 days before taking the remaining doses of that potency following the same dose schedule as stated above. In case of further appearance of new sign(s) and/or symptom(s), the same procedure as stated above was followed until the consumption of 56 doses of that potency by the volunteer. If the volunteer was experiencing the same symptom(s) what he/she had already shown, he/she was asked to stop the current quota and switch over to the next quota after a washout period of 14 days.

Each prover was interrogated by the proving master about the appearance of new sign(s) and/or symptom(s) or the progress of symptoms, and they were noted down in "Symptoms Elaboration Proforma" with respect to appearance and disappearance of symptoms, their location, sensation/character, modalities, concomitants, extension of symptoms, causation, clinico-pathological findings and other treatment taken.

Before commencing the administration of subsequent potencies (subsequent phase) of the drug, the volunteers remained on a washout/rest period (it should be a symptom-free period between two phases of drug proving in which a volunteer does not take the drug) for 14 days and started taking the next potency following the same procedure as mentioned above, until completion of 56 doses. The same procedure was followed for the third phase.

The symptoms recorded in prover's day book proforma were verified by the proving master and completed through further interrogation with the volunteers, with respect to their location/sensation/modalities/concomitants, if any, in Symptoms Elaboration Proforma.

During the course of proving, the volunteers were referred for specific laboratory investigation(s) to rule out any pathological cause for appearance of new sign(s) and/or symptom(s). Laboratory tests were performed to identify any correlation between the subjective and objective changes during the course of proving. The opinion of the experts (honorary

consultants) was also obtained, wherever needed.

After completion of trial of all potencies, the volunteers underwent TME. On completion of all the respective quotas of the proving program, the compilation of data recorded in prover's day book proforma Symptoms elaboration proforma, pathological report sheets, and terminal medical examination sheets were analysed CCRH headquarters by the drug proving-cum-data processing cell. After decoding, the signs and/or symptoms experienced by the volunteers kept on the drug were separated from those experienced by the volunteers kept on placebo. The signs and/or symptoms, which were common to both the groups (i.e. placebo as well as drug groups), were not taken into consideration while compiling the symptomatology of the proved drug.

Management of Adverse Effects

A vial of antidote was sent with each quota to each centre. The proving master gave antidote to the volunteer if symptoms continued for a long time or their intensity was too much to cause discomfort. The proving master was also directed to take the advice of honorary consultants and to get laboratory investigations done, if required. During proving, no serious adverse events occurred.

Pathogenetic Effects

Pathogenetic effects (proving symptoms) are defined as all the changes in clinical events and laboratory findings reported by the volunteers during a HPT and recorded in the final report. The incidence of pathogenetic effects per volunteer is defined as the total number of findings observed in the trial divided by the total number of provers who developed symptoms.[5] So, the incidence in this proving was 2.45 per volunteer. The total number of symptoms produced by 11 provers was 27. Among these, 21 symptoms [Table 1] were produced during the second quota, i.e. by 6C, and 6 symptoms [Table 2] were produced during the third quota, i.e. by 30C.

Pathogenetic effects were deduced from the following:

1. Comparison of symptoms developed in the placebo phase with the symptoms developed during the intervention phases (intra-prover comparison)
2. Comparison of symptoms developed by the provers in the control group (for all phases) with those of provers in the actual drug trial (inter-prover comparison).

RESULTS

At Drug Proving Unit (H), Bhubaneswar, out of 16 volunteers, 3 reported symptoms. At Central Research Institute (H), NOIDA, out of 17 volunteers, 8 reported symptoms. No symptom was reported by any prover at Homoeopathic Drug Research Institute, Lucknow.

The following symptoms were observed during the drug proving.

N.B.: In the first parentheses, the first number given after every symptom denotes the number of volunteers who developed that particular symptom and the second number denotes the potency used. In the second parentheses, the first number denotes the doses after which that particular symptom was produced and the second number denotes the duration (in days) for which the symptom lasted.

Head

- Headache from forehead to occiput with a sensation as if blood rushes over head, *agg.* lying down; *amel.* by pressing (1, 6C) (40, 1)
- Throbbing pain in frontal and temporal regions as if head would burst, *agg.* looking down, noise, talking; *amel.* lying down (1, 6C) (40, 1)
- Bursting pain in the whole head, *agg.* exertion, tension; *amel.* rest, pressure; accompanied with weakness, nausea and restlessness (1, 6C) (25, 1)
- Pressing pain in vertex, *agg.* exertion; *amel.* taking tea (1, 6C) (21, 1)
- Heaviness in forehead, *amel.* pressure, tight bandage (1, 6C) (31, 1)
- Heaviness and throbbing pain in occipital region, *agg.* talking; *amel.* hard pressure. Headache gradually increased (1, 6C) (42, 2)
- Throbbing pain in both temples with heaviness, *agg.* noise; *amel.* lying down (1, 6C) (54, 1)
- Throbbing pain in frontal and temporal regions with a sensation as if head would burst, *agg.* by looking down, noise, talking; *amel.* lying down quietly, closing eyes (1, 6C) (11, 1)
- Throbbing pain in frontal region of head, *agg.* by moving the head; *amel.* lying down. It was accompanied with nausea (1, 6C) (48, 1)
- Bursting pain in the whole head, *agg.* exertion; *amel.* rest (1, 30C) (20, 1)
- Heaviness and bursting pain in occipital region, *agg.* talking, laughing; *amel.* hard pressure (1, 30C) (36,1)

Eye

- Intermittent twitching of left eye lid; accompanied

Table 1: Pathogenetic effects of 6C (second quota drug) in chronological order (according to doses taken)

Location	Symptoms	No. of doses after which the symptom developed
Head	Throbbing pain in frontal and temporal regions with a sensation as if head would burst, *agg*. by looking down, noise, talking; *amel*. lying down quietly, closing eyes	11
Nose	Coryza with watery discharge and sneezing with a sensation of burning and itching in nose, *agg*. evening, dust; *amel*. lying down. It was accompanied with watery discharge from eyes, dryness of throat and decreased thirst. Along with this, there was no desire to do any mental or physical work	13
Extremities	Aching and tearing pain in calf muscles, *agg*. rest; amel. tight bandage	18
Head	Pressing pain in vertex, *agg*. exertion; *amel*. taking tea	21
Head	Bursting pain in the whole head, *agg*. exertion, tension; *amel*. rest, pressure. It was accompanied with weakness, nausea and restlessness	25
Back	Pain and soreness in lower back (lumbar region), *agg*. walking, sitting for long; *amel*. warm application, lying down. Pain extended from lower back to thighs	25
Extremities	Pain in ankles with burning in soles, *agg*. pressure, walking; amel. sitting bare feet. It was accompanied with restlessness	25
Head	Heaviness in forehead, *amel*. pressure, tight bandage	31
Eye	Intermittent twitching of left eye lid. It was accompanied with intense thirst for little quantity at frequent intervals	36
Head	Headache from forehead to occiput with a sensation as if blood rushes over head, *agg*. lying down; *amel*. by pressing	40
Head	Throbbing pain in frontal and temporal regions as if head would burst, *agg*. looking down, noise, talking; *amel*. lying down	40
Extremities	Aching and tearing pain from thighs to legs, esp. calf muscles, *agg*. lying down; *amel*. fast walking, tight bandaging	40
Generalities	Cramping pain in the whole body, *agg*. walking; *amel*. lying down. It was accompanied with nausea	41
Head	Heaviness and throbbing pain in occipital region, *agg*. talking; *amel*. hard pressure. Headache gradually increased	42
Throat	Burning sensation in throat, *agg*. at night; *amel*. drinking cold water, but it returned within 10 min	44
Abdomen	Dull aching pain in the lower abdomen, *agg*. motion, bending forward; *amel*. pressure. Next day, same symptom with nausea, *agg*. motion; amel. pressure	45
Head	Throbbing pain in frontal region of head, *agg*. by moving the head; *amel*. lying down. It was accompanied with nausea (a/f eating oily and spicy food)	48
Nose	Coryza with slight acrid watery discharge more from right nostril, *agg*. warm; *amel*. open air	53
Cough	Dry cough	53
Head	Throbbing pain in both temples with heaviness, *agg*. Noise; *amel*. lying down	54
Nose	Coryza with sneezing and watery nasal discharge with itching sensation in nose, *agg*. cold water; *amel*. lying down	54

with intense thirst for little quantity at frequent intervals (1, 6C) (36, 3)

Nose

- Coryza with slight acrid watery discharge more from right nostril, *agg.* warm; *amel.* open air (1, 6C) (53, 1)
- Coryza with watery discharge and sneezing with sensation of burning and itching in nose, *agg.* evening, dust; *amel.* lying down; accompanied with watery discharge from eyes, dryness of throat and decreased thirst; no desire to do any mental or physical work (1, 6C, 30C) (13, 1) (45, 1) [*The first bracket denotes that this particular symptom was produced by both 6C and 30C potencies in one volunteer; the second bracket denotes the no. of doses of 6C potency and duration of that symptom during trial; the third bracket denotes the no. of doses of 30C potency and duration of that symptom during trial*].
- Coryza with sneezing and watery nasal discharge with itching sensation in nose, *agg.* cold water; *amel.* lying down (1, 6C) (54, 1)
- Stoppage of nose, pressing feeling at the root of nose, *agg.* lying down; *amel.* taking tea. It was accompanied with bursting pain in the whole head. Next day, there was yellowish-green

Table 2: Pathogenetic effects of 30C (third quota drug) in chronological order (according to doses taken)

Location	Symptoms	No. of doses after which the symptom developed
Face	Mild painful small-sized pimples on face	16
Head	Bursting pain in the whole head, *agg*. exertion; *amel*. rest	20
Head	Heaviness and bursting pain in occipital region, *agg*. talking, laughing; *amel*. hard pressure	36
Nose	Coryza with watery discharge and sneezing with sensation of burning and itching in nose, *agg*. evening, dust; *amel*. lying down. It was accompanied with watery discharge from eyes, dryness of throat and decreased thirst. Along with this, there was no desire to do any mental or physical work	45
Nose	Stoppage of nose, pressing feeling at the root of nose, *agg*. lying down; *amel*. taking tea. It was accompanied with bursting pain in the whole head. Next day, yellowish-green discharge from the nose with frontal headache	47
Cough	Cough with yellowish-green expectoration	47

discharge from the nose with frontal headache (1, 30C) (47, 3)

Face

- Mild painful small-sized pimples on face (1, 30C) (16, 3)

Throat

- Burning sensation in throat, *agg.* at night; *amel.* drinking cold water, but it returned within 10 minutes (1, 6C) (44, 7)

Abdomen

- Dull aching pain in lower abdomen, *agg.* motion, bending forward; *amel.* pressure. Next day, same symptom with nausea, *agg.* motion; *amel.* pressure (1, 6C) (45, 2)

Cough

- Dry cough (1, 6C) (53, 1)
- Cough with yellowish-green expectoration (1, 30C) (47, 2)

Back

- Pain and soreness in lower back (lumbar region), *agg.* walking, sitting for long; *amel.* warm application, lying down; extending from lower back to thighs (1, 6C) (25, 3)

Extremities

- Aching and tearing pain in calf muscles, *agg.* rest; *amel.* tight bandage (1, 6C) (18, 1)
- Aching and tearing pain from thighs to legs, especially calf muscles, *agg.* lying down; *amel.* fast walking, tight bandaging (1, 6C) (40, 1)
- Pain in ankles with burning in soles, *agg.* pressure, walking; *amel.* sitting bare feet; accompanied with restlessness (1, 6C) (25, 1)

Generalities

- Cramping pain in the whole body, *agg.* walking; *amel.* lying down; accompanied with nausea (1, 6C) (41, 2)

DISCUSSION

The drug was able to produce symptoms both in 6C and 30C. Maximum symptoms were produced by 6C potency. The drug was able to produce more symptoms of head and nose. Symptoms in head were marked by congestion, with surging of blood to head producing mild heaviness and bursting sensation. Throbbing also corroborated the hyperemic condition of head. Discharges from the nose had acrid character and produced itching and burning sensation. Amelioration from lying down can be considered as the general modality that was observed in head, nose, back and general muscular pains. Among the 11 volunteers who developed symptoms, 3 volunteers developed maximum symptoms in different systems.

CONCLUSION

The symptoms produced during the trial will benefit the research scholars and clinicians. Those proving symptoms need verification through application in different Clinical Verification Trails and will add their value in prescription. Further observation of new clinical symptoms after its therapeutic use may enhance its applicability in day-to-day practice.

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साइक्लोस्पोरिन

उद्देश्यः स्वस्थ मनुष्य पर होम्योपैथी पोटेंसी में साइक्लोस्पोरिन दवा की विकारी प्रतिक्रिया पर प्रकाश डालना।

सामग्री एवं विधिः केन्द्रीय होम्योपैथी अनुसंधान परिषद् द्वारा एक डबल ब्लांइड प्लासिबो नियंत्रित परीक्षण के माध्यम से साइक्लोस्पोरिन दवा को प्रमाणित किया गया है। अध्ययन को दो केन्द्रों पर आयोजित किया गया। नियमित प्रयोगशाला जाँच और चिकित्सक विशेषज्ञों द्वारा पूर्व परीक्षण चिकित्सा अध्ययन आयोजित करने के बाद 50 स्वस्थ स्वयंसेवकों पर दवा को दो पोटेंसियों (6सी और 30 सी) में प्रमाणित किया गया। पहले चरण में, स्वयंसेवकों को प्लासिबो की 56 खुराक (14 दिन के लिए प्रतिदिन 4 खुराक) दी गई। अगले दो चरणों में, प्रत्येक पोटेंसी या प्लासिबो की 56 खुराक (14 दिन के लिए प्रतिदिन 4 खुराक) दी गई। परीक्षण अवधि के दौरान उत्पन्न लक्षणों को स्वयंसेवकों द्वारा नोट किया गया और प्रमाणकर्ताओं द्वारा विस्तृत किया गया। सभी तीन केन्द्रों से प्राप्त आँकड़ों को डिकोडिंग के बाद सीसीआरएच, मुख्यालय के प्रमाणन व डेटा प्रोसेसिंग सेल में संकलित किया गया।

परिणामः कुल 50 प्रमाणकर्ताओं में से 33 को वास्तविक दवा परीक्षण पर और 17 को प्लासिबो पर रखा गया। कुल 11 प्रमाणकर्ताओं में लक्षण प्रकट हुए। यह दवा शरीर के अधिकांश भागों में (प्रत्येक पोटेंसी में) लक्षण उत्पन्न करने में सक्षम सिद्ध हुई।

निष्कर्षः प्रमाणन परीक्षण अवधि के दौरान उत्पन्न विकारी प्रतिक्रियाओं से साइक्लोसपोरिन दवा के उपयोग का दायरा बढ़ाया और इससे अनुसंधान विद्वानों और चिकित्सकों को फायदा होगा। चिकित्सीय सत्यापित होने के पश्चात् यह लक्षण और अधिक उपयोगी साबित होंगे।

खोजशब्दः साइक्लोस्पोरिन, औषधि प्रमाणन, होम्योपैथी, होम्योपैथी विकारी परीक्षण, प्रतिरक्षी अवरोधक, विकारी प्रभाव।