

DRUG PROVING

POTHOS FOETIDUS – A multicentric double blind Homoeopathic Pathogenetic Trial

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Objective: To elicit the pharmacodynamic response of the drug *Pothos foetidus* on healthy human beings in non-toxic doses.

Methodology: Drug was proved through a double-blind method. The study was conducted at two centres. The drug was proved in three potencies (6C, 30C and 200C) on 25 volunteers who were selected and declared apparently healthy during their pre-trial medical examination by specialists and through their routine pathological investigations. The volunteers consumed 56 doses (four doses per day for fourteen days) of each potency (6C, 30C and 200C) in three stages for a varying period. The symptoms generated during the trial period were noted by the volunteers and elaborated and cross examined by the Proving Masters. The data obtained from both the centers was compiled at proving-cum-data processing cell at CCRH headquarters after de-coding.

Observations: Out of the 18 provers who were on actual drug trial, 11 manifested symptoms. Drug was able to produce symptoms in each potency more or less on every part of the body. Only a few symptoms appeared in more than one prover. Some of the symptoms have been reprovved which are mentioned in the fragmentary provings published in different literatures.

Conclusion: Pharmacodynamic responses, elicited (new and reprovved) during the proving trial will add to the literature available on the drug and benefit the research scholars and clinicians. This also needs verification through clinical trials.

Key words: homoeopathy; pharmacodynamic effect; homoeopathic pathogenetic trial; drug proving; *pothos foetidus*.

Introduction

Dr. Hering introduced this remedy to Homoeopathy¹. In the 19th century the U. S. Pharmacopoeia listed eastern skunk cabbage as the drug "dracontium". It was used in the treatment of respiratory diseases, nervous disorders, rheumatism and dropsy. In North America and Europe, skunk cabbage is occasionally cultivated in water gardens. Skunk cabbage was used extensively as a medicinal plant, for seasoning, and as a magical talisman by various tribes of Native Americans. The roots are toxic and the leaves may burn the mouth, so the leaves may be dried and used in soups and stews.² The plant is

being traditionally used as a medicinal plant. The roots are being used in cases of asthma, leaves being applied on the ulcers. The seeds have an antispasmodic action, so useful in spasmodic cough.³

Objective

To elicit the pharmacodynamic response of the drug *Pothos foetidus* on apparently healthy human volunteers, in non-toxic doses.

Literature review

Botanical name : *Pothos foetidus* Mich.
Family : Araceae¹
Common names :
English : Bear's foot¹
French : Raccine de pothos fetide¹

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German : Stinkende drachenwurzel¹
Latin : Ictodus foetidus, Arum
americanum⁴

Description

Stemless and sub-aquatic; root vertically fibrous, truncate. Leaves smooth, green ovate-cordate, enlarging protected by large glaucous, spatulate veinless bracts. Spathe ovoid, roundish hooded, obliquely acuminate; plaited involutely; auriculate at the base, thick and spongy, livid purple, spotted with blotches of pale green. Spadix pedunculate, simple almost spherical; bracts none. Flowers imbricate, adnate calyx 4-parted divided to the base, compressed at the apex, emerginate later becoming very thick, petals none. Stamens 4, opposite the calyx lobes, filaments subulate, flat; anthers exerted, short oblong oval 2 celled; style thick, quadrangular, acuminate; stigma minute and pubescent. Seed naked, large, round, enclosed in the common receptacles. Corculum small, involute, erect, umbilicately attached to a large solid, corneous perisperm¹.

Distribution

North America from Canada to Carolina¹. Exclusively a native of North America; found in abundance in swamps, meadows and ditches. Renowned for odour, which is scarcely less offensive than that of skunk.⁴

Part used in Homoeopathy

Root¹

Materials and Methods

Location and duration of study

The proving was conducted in Drug Proving Research Unit (H), Midnapore and Regional Research Institute (H), New Delhi during 2001-02 and 2002-03 respectively.

Participants

Twenty five apparently healthy volunteers, of both sexes, between the age group of 18-50 years, comprising of 20 males and 05 females, were enrolled for this study. Pre-trial Medical Examination (PME) and Terminal Medical Examination (TME) of the volunteers were carried out by General Physicians, Psychiatrists, Cardiologists, Ophthalmologists, ENT Specialists, Dermatologists, Gynaecologists and Radiologists at both the centers to ascertain their health status.

Drug

Pothos foetidus (6C, 30C and 200C potencies) were procured from M/s. Dr. Willmar Schwabe India Pvt. Ltd., India, in 100 ml. sealed phial of each dilution. Globules (number 30) were medicated with these attenuations at headquarters office and sent to Drug Proving Units in coded phials (verum) along with placebo (control).

Placebo

Placebo was made up of plain globules (number 30) moistened with plain dispensing alcohol (unsuccussed).

Design

The study was conducted through placebo controlled 'double blind technique'.

Methods

Before commencing the study, all provers were screened as per the drug proving protocol of CCRH. Written informed consent from each volunteer was obtained before starting the proving. Pre-trial Medical Examination (PME) was conducted to confirm health status of the volunteers. Volunteers declared healthy, were enrolled in the study. Out of 25 volunteers, 18 were kept on drug (verum) and 07 were on placebo (control). All the volunteers were assigned code numbers and the coded drugs (including placebo) of different potencies were supplied in separate glass phials bearing code numbers of the respective volunteers.

The study consisted of *three stages* of three different potencies viz. 6C, 30C and 200C. Each potency of the drug was given in 56 doses to be taken 4 doses per day till the appearance of symptoms. So the duration of each stage varied according to presentation and duration of symptoms.

The volunteers were asked to take 4-6 globules of a particular potency of the coded drug, four times a day, dry on tongue.

The volunteers were instructed to note down the details of their feelings/changes in mind and body, after taking drug in 'Prover's Day Book Proforma' daily.

- *If sign(s) symptoms(s) appeared:*

The volunteers were asked to stop taking the drug as soon as they felt any change or any sign(s) and/or symptoms(s) developed during the trial.

The volunteer noted down the sequence of the appeared new sign(s) and/or symptoms(s), their progress and the number of doses after which the sign and/or symptoms(s) appeared with date, time of onset and duration for which they persisted. Intake of drug remained suspended till the sign(s) and/or symptoms(s) totally disappeared.

After disappearance of sign(s) and/or symptom(s) developed by the drug, the volunteer waited for a further period of 07 days before resuming the intake of remaining doses of that potency. The volunteer took the remaining doses of the drug following the same dose schedule as stated above. In case of further appearance of new sign(s) and/or symptom(s) or re-appearance of the earlier sign(s) and/or symptom(s), the same procedure as stated above was followed till the consumption of 56 doses of that potency by the volunteer.

• *If no sign(s)/ symptoms(s) appeared:*

If no symptom was observed, the volunteers should note down as 'No Symptom' with date and time of intake of the respective dose of the drug.

Before commencing the administration of subsequent potencies (subsequent stage) of the drug, volunteers remained on a rest period (it is a symptom free period between 2 stages of drug proving in which a volunteer does not take any drug) for 14 days and started taking next potency in the same procedure as mentioned above, till completion of 56 doses.

Same procedure was followed for the 3rd potency.

Each volunteer was interrogated by the Proving Master to verify the sign(s) and/or symptom(s) recorded by the volunteer. The symptoms recorded in 'Prover's Day Book Proforma' were verified by the Proving Masters and completed with the details related to their location/ sensation/ modalities and 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 symptom(s). Laboratory tests were performed to correlate between the subjective and objective changes during the course of proving. The expert opinion of the honorary consultant(s) was obtained, where it was needed.

After completion of trial of all potencies, the volunteers were examined by the specialists again. This is called 'Terminal Medical Examination' (TME).

On completion of all the respective stages of the proving, the compilation of data recorded in 'Prover's Day Book Proforma', 'Symptoms Elaboration Proforma', 'Pathological Report Sheets' and 'Terminal Medical Examination sheets', was done at the headquarters by the Drug Proving-cum-Data Processing cell. After decoding the proved drug, the sign(s) and/or symptom(s) generated by the volunteers kept on the drug were separated from those generated by the volunteers kept on placebo. The sign(s) and/or symptom(s) 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 drug.

Results

At Drug Proving Research Unit (DPRU), Midnapore out of 14 volunteers, 06 volunteers reported symptoms, and in Regional Research Institute (RRI), New Delhi out of 11 volunteers, 05 volunteers reported symptoms consequent upon the administration of drug.

The following symptoms were observed during the drug proving

- In parenthesis, 1st number after every symptom denotes number of volunteers produced that particular symptom and 2nd number denotes potency used.
- Agg.: aggravation, amel.: amelioration
- Symptoms produced during the pathogenetic trial of the drug were compared with the homoeopathic literature cited in the reference and those symptoms which were found in the literature, shown in **bold**, superscripted with a numerical that refers to the respective literature.

Mind

- Feeling as if injured with a knife while using it. (1, 200C)
- **Irritable**^{6,7,8} (1,200C)

Vertigo

- **Vertigo**^{3,5,9} with nausea (2, 30C & 200C)

Head

- **Headache**^{5,6,7,8}, *agg.* noon (1, 200C)
- Pain in whole head, *agg.* noon (1,200C)

- Aching whole head, *agg.* evening (1,200C)
- Aching in head with pain in throat (1,200C)
- Headache, *agg.* night and remains whole night (1,6C)
- Pinching pain in left side of head (1,30C)
- **Frontal headache**^{5,7}, *agg.* morning, *amel.* by hot milk (1,200C)
- Bursting pain in right temporal region. (1,30C)

Nose

- **Sneezing**^{3,5,6,8,9} frequent, *agg.* morning (1, 200C)
- Sneezing, *agg.* evening (1, 200C)
- Sneezing with acrid nasal discharge, *agg.* noon (1, 30C)

Face

- Papular eruptions with itching on face during menses (1, 200C)

Mouth

- **Burning sensation**⁷ in mouth with ulcer inside the lower lip (1, 6C)

Throat

- **Pain in throat**^{6,8} with headache, *agg.* evening (1, 200C)
- Aching in throat, *agg.* morning (1, 200C)
- Pain with soreness in throat, *agg.* morning after waking up (1, 200C)

Stomach

- **Vomiting**^{3,5,9} with **nausea**^{3,5} (2,200C)
- Vomiting frequent with nausea (1,30C)
- Vomiting frequent, *agg.* evening (1,200C)

Abdomen

- Accumulation of gas with rumbling, heaviness in lower abdomen, gripping pain, *agg.* eating, *amel.* passing flatus (1, 200C)

- **Pain in abdomen**⁵, colicky (1, 30C)
- Rumbling sensation in abdomen with flatulence and loose stool (1, 200C)

Rectum

- Constipation, stool passes with great difficulty. (1, 200C)
- Stool, constipated. (1, 6C)
- Painless frequent stool. (1, 200C)
- Frequent desire for stool (1,200C)

Stool

- Loose stool, *agg.* night (1, 200C)
- Watery stool (2, 200C)
- Blackish stool (1, 200C)
- Stool hard (1, 6C)
- Watery, loose stool (1, 200C)

Urethra

- Burning pain in urethra during urination (1, 200C)

Cough

- **Cough**^{3,5}, *agg.* morning with rattling in chest, yellow expectoration (1, 200C)
- Mild cough with sore throat (1, 200C)

Chest

- **Pain in chest**^{3,6,7,8} (lower part), *agg.* morning (1,30C)

Extremities

- Eruptions on thighs with slight itching (1, 200C)
- Pain in legs, *amel.* by pressure (1, 200C)

Sleep

- Disturbed sleep (1, 200C)
- Disturbed sleep due to cold/coryza (1, 200C)
- Unrefreshing, sleepy with desire for lying down (1, 200C)

Fever

- Fever with headache and sneezing, *agg.* evening (1,200C)

Skin

- Red eruptions^{3,5} all over the body with itching and burning, *amel.* applying water (1, 200C)

Generalities

- Fatigue, no desire to work, *amel.* pressure (1, 30C)
- Laziness, no desire to work (1, 200C)
- Pain all over the body with throat pain. (1, 200C)
- Weakness feeling with headache (1, 30C)

Discussion

Drug was able to produce symptoms in 6C, 30C and 200C potencies more or less on every part of the body. Only 03 symptoms viz. *vertigo with nausea, vomiting with nausea* and watery stool appeared in more than one prover. 13 symptoms were re-proved which are already in the available literature of fragmentary proving.

The drug seems to be indicated in vertigo, headache, coryza, aphthous, cough and fever. Drug has also shown affinity for accumulation of gas with rumbling, colicky pain in abdomen, constipation and watery stool. It also produces disturbed sleep. These symptoms may help in clinical application of the medicine.

Conclusion

Symptoms appeared (new and re-proved) during the trial will add to the available literature on this medicine and benefit the research scholars and

clinicians. These proved symptoms need further verification through clinical application in different settings.

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