

DRUG PROVING

Paraffin: A Multicentric double blind Homoeopathic Pathogenetic Trial carried out by CCRH

Rajpal¹, V.A. Siddiqui¹, N.R. Dey², K.C. Das³, Yogendra Rai⁴, Vinay Kr Singh⁵

1. Research officer (H), CCRH Headquarters, New Delhi, India
2. Research officer (H), Drug Proving Research Unit, Kolkata, West Bengal, India
3. Research officer (H), Drug Proving Research Unit, Midnapore, West Bengal, India
4. Research officer (H), Drug Proving Research Unit, Ghaziabad, Uttar Pradesh, India
5. Senior Research Fellow, CCRH Headquarters, New Delhi, India

Objective: Objective of the study was to elicit the pharmacodynamic response of the drug Paraffin on healthy human volunteers in non-toxic doses.

Methodology: Drug was proved through a double-blind method and multi-centric study. Trial drug was proved in three potencies (6C, 30C and 200C) on 43 volunteers who were declared apparently healthy during their pre-trial medical examination by medical specialists. 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 different centers were compiled at proving-cum-data processing cell at CCRH headquarters after de-coding.

Observation: Out of the 30 provers who were on actual drug trial, 13 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 literature.

Conclusion: Pharmacodynamic response is elicited from every part of the body. Symptoms appeared (new and reprovved) during the proving trial will add to the literature available on the drug and benefit the research scholars and clinicians. The symptoms need to be verified through clinical application in different clinical conditions.

Key words: homoeopathy; pharmacodynamic effects; homoeopathic pathogenetic trial; drug proving; paraffin.

Introduction

This medicine was introduced by Dr. Wahle of Germany, who was the chemist of Dr. Hahnemann. He proved it but never published it and gave the manuscript to his son who in turn gave it to Dr. Held. Dr. Held translated it into Italian and Dr. W.F. Robinson translated it into English.^{1,2}

Paraffin is used clinically in Unani system of Medicine as an anti-inflammatory, laxative, analgesic^{3,4}.

Sensitive reactions and acne have been reported following the topical application. Granulomatous reactions following absorption or injection and lipoid pneumonia following aspiration have occurred.⁵

A systematic proving of the drug in potencies was necessary to get its pathogenetic power, so Central Council for Research in Homoeopathy undertook its pathogenetic trial through its three centers.

Address for correspondence:

Director

Central Council For Research In Homoeopathy

61-65, Institutional Area, D-Block, Janakpuri,

New Delhi - 110058

Email : ccrh@del3.vsnl.net.in

Objective

To elicit the pharmacodynamic response of the drug Paraffin on healthy human volunteers in non-toxic doses.

Synonyms

English: Paraffin wax, hard paraffin
French: Paraffine

Description

It is a mixture of solid hydrocarbons having the general formula C_nH_{2n+2} ; it is obtained from petroleum, although formerly it was also obtained by the destructive distillation of wood, peat, coal and other organic materials. Paraffin occurs as a colourless or white, more or less translucent mass. It is odourless and tasteless, is slightly greasy to touch and burns with a luminous flame. Its melting range is between 47°C and 65°C. It is freely soluble in chloroform, ether, benzene, volatile oils and in most warm fixed oils. It is slightly soluble in dehydrated alcohol and is insoluble in water and alcohol. It is miscible when melted with wax and fats. Paraffin is slowly attacked only by concentrated Sulphuric Acid, and not at all by dilute Nitric Acid.^{5,6,7}

Materials and Methods

Location and duration of study

The drug was proved at Drug Proving Research Units (H), located at Kolkata (W.B.), Ghaziabad (U.P.) and Midnapore (W.B.) during 2000-01, 2001-02 and 2002-03 respectively.

Participants

Forty-three apparently healthy volunteers, of both sexes, between the age group of 18-50 years, comprising of 28 males and 15 females were enrolled for this study. Pre-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 all the three centers to ascertain their health status.

Drug

Paraffinum (6C, 30C and 200C potencies) were procured from M/s. Dr. Willmar Schwabe India Pvt. Ltd., India, in 100 ml. sealed phials of each dilution. Globules (number 30) were medicated with these attenuations at headquarter 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 (unsuccessful).

Design

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

Method

Before commencing the study, all provers were screened as per the drug proving protocol of CCRH. Ethical approval was obtained and '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 who were declared healthy, were enrolled in the study. Out of 43 volunteers, 30 were kept on drug (verum) and 13 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 and the duration of each stage was 14 days (4 doses daily for 14 days i.e. 56 doses).

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 his/her 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 volunteers 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 the disappearance of the sign(s) and/or symptom(s) developed by the drug, the volunteers

waited for a further period of 07 days before resuming the remaining doses of that stage. The volunteers took the remaining doses of the drug again in the same dosage 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 volunteers.

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

If no symptom was observed, even then the volunteers noted 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 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 (next) potency.

Each volunteer was interrogated by the Proving Master every day 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 Master and completed with the details related to their locations/ sensations/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 cause(s) for appearance of symptom(s). Laboratory tests were performed to identify any correlation between the subjective and objective changes during the course of proving. The expert opinion of the honorary consultant(s) was obtained, where it was required.

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

On completion of all the 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 CCRH 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 appeared in 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), Kolkata, out of 14 volunteers, 07 volunteers manifested symptoms. At DPRU, Midnapore, out of 14 volunteers, 05 volunteers reported symptoms, and in DPRU, Ghaziabad, out of 15 volunteers, only 01 volunteer 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 who 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, are printed **bold**, superscripted with a numerical that refers to the respective literature.

Mind

- No desire to work, drowsiness with weakness, gloomy (1,200C)

Vertigo

- Vertigo on turning head, on rising from sleep (1, 6C)
- Vertigo, *agg.* morning, rising from sitting, *amel.* sleeping (1,6C)
- Vertigo accompanied with fever (1, 30C)

Head

- **Heaviness of head**¹ (1, 6C, 200C)
- Heaviness of head, *agg.* morning, disappeared suddenly (1, 200C)
- **Pain in head**^{8,9}, *amel.* by lying down (1, 6C)
- Pain in head, *agg.* morning. (1, 6C)
- Throbbing pain in frontal region (3, 6C, 30C), *amel.* by nasal discharge. (1, 6C)
- Pain in head, *amel.* by taking bath (1,6C)

- Severe pain in forehead, *amel.* by pressure on forehead, after sleep. Heaviness and uneasiness feeling. (1,200C)
- Throbbing pain in temple and occiput. (1,200C)

Eye

- Heaviness of eyes (1, 6C)
- **Itching**² of left eye lid (1,6C)
- **Pain with redness and agglutination of eyes**¹, *amel.* by washing with warm water (1,6C)
- Redness of right eye with rawness feeling (1,200C)

Ear

- Pain in ears with stuffed up feeling (1,200C)

Nose

- Crawling sensation in nose, nostrils blocked (1, 30C)
- Whitish yellow mucous discharge from nose. (1, 6C)
- Nasal discharge, watery with uneasiness, *agg.* by heat, motion (1, 30C)
- Watery nasal discharge which later became whitish and yellow in colour (1,6C)
- Sneezing with headache, watery discharge from nose followed by thick nasal discharge (1,6C)
- Sneezing continuous with pain in throat (1,200C)

Face

- Herpes like eruptions on the upper lip (1,200C)
- Burning heat in face with formication on lips (1,30C)
- Fever blisters (1, 6C)

Mouth

- **Bitter taste**^{2,8,10} (2, 6C & 30C)
- Dryness of mouth with loose stool (1, 200C)
- Red ulcers inside the cheek near last tooth on right side (1, 6C)

Throat

- Tickling sensation in throat, *agg.* by talking, *amel.* by drinking water, covering the throat, warmth (1, 6C)
- **Dryness in throat**^{1,9} with raw sensation, *agg.* by drinking water. Pain in throat, *agg.* by empty swallowing; *amel.* swallowing solid things (1,6C)
- **Pain in throat**¹⁰, *agg.* talking, swallowing; , *amel.* taking warm drink, lying down (1,200C)
- Burning pain in throat after vomiting (1,200C)
- Slight pain in throat, *agg.* by swallowing (1,6C)
- Throat congested (1,6C)

Stomach

- **Sour eructations**², *agg.* morning, evening. Nausea (1,200C)
- **Sour eructations, *agg.* after eating**^{1,2}, uneasy feeling, vomiting of sour water, *agg.* mouth washing (1,200C)
- **Pain in chest with sour eructations**¹⁰ (1,200C)
- Nausea and vomiting, sour eructation, *agg.* after eating, *amel.* drinking lemon water (1,6C)
- Nausea with headache; thirsty but takes small amount of water (1,200C)
- Mild loss of appetite with belching (1,30C)
- Loss of appetite, retching (2,6C & 30C)
- Very much thirsty (1,30C)
- Thirst for cold water with dryness of mouth (1,200C)
- **Thirstlessness**⁹ (1,6C)

Abdomen

- Pain in right side of abdomen (1, 200C)
- **Colicky pain in abdomen**^{1,2} with fever (1, 30C)
- **Gripping pain in abdomen**^{1,2} with loose stool (1, 200C)

Rectum

- **Constipation**^{2,8,9,10} (1, 30C & 200C)
- Constipation, first part of stool hard. (1, 30C)
- **Urge for stool**¹⁰, but passes small quantity without satisfaction (1, 6C)
- **Unsatisfactory stool**¹⁰ (1,30C)
- **Severe constipation, great straining but no stool passes**^{2,8,9,10} (1,200C)
- Flatulence (1,30C)

Stool

- **Hard stool**¹, small blackish (1, 200C)
- Loose stool, **frequent**^{8,9} (2, 200C)

Urine

- Urine red, turbid (1, 200C)

Urethra

- Burning sensation in urethra (1, 30C)

Larynx

- Hoarseness of voice, *amel.* by warm drinks (1,30C)

Cough

- Cough with fever (1, 6C)
- Violent cough with fever (1, 30C)

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- Dry spasmodic cough, *agg.* by cold air. (1, 6C)
- Dry spasmodic cough, *agg.* evening, night (1,6C)
- Severe paroxysmal cough with expectoration, *agg.* morning (1,200C)

Expectoration

- Greenish yellow thick expectoration (1,6C)

Chest

- Rattling in the chest (1,6C)

Neck

- Itching at nape of neck, crawling sensation (1,6C)

Extremities

- Hands and feet feel cold under the fan (1, 6C)
- Dry itching in legs, *amel.* by rubbing (1, 6C)
- Drawing pain in left shoulder joint (1, 200C)
- Drawing pain in elbows and knees, *agg.* straining, cold exposure, *amel.* pressure, massage (1,30C)

Sleep

- Disturbed sleep (1, 200C)
- **Sleepiness**⁹ (1,30C)
- Sleepiness with headache (1,30C)

Fever

- **Fever**^{1,9} with burning sensation all over the body (1, 30C)
- Fever with chill, bodyache and headache, *amel.* in evening (1,6C)
- Fever with bodyache (1,6C)
- Fever with bodyache and chilliness, *agg.* evening (1,30C)
- Fever with cough (1,30C)
- Fever with sneezing and headache (1,6C)
- Bodyache with feverish feeling, general weakness, *agg.* by heat, motion, *amel.* by rest, pressure (1, 30C)

Skin

- Mild itching sensation all over the body, more on lower legs, *agg.* by cold air (1,6C)

Generalities

- Pain all over the body (1, 30C)
- Bodyache, *agg.* morning. (1, 200C)
- Lethargic feeling, no desire to work, desire to take rest (1, 200C & 6C)

- Uneasiness in body (1,200C)
- **Weakness**¹ (1, 6C & 30C)

Discussion

Paraffin was able to produce symptoms in 6C, 30C and 200C potencies more or less on every part of the body. Only four symptoms viz. *throbbing pain in forehead; bitter taste; loss of appetite with retching and loose and frequent stool*, appeared in more than one prover. Twenty two symptoms were reproved which are already in the literature available from fragmentary proving.

The drug seems to be indicated in vertigo, headache, conjunctivitis, coryza, throat pain, cough and fever. The drug has also shown affinity on digestive system with acidity, loss of appetite, sour eructation, nausea and vomiting, constipation and loose stool. 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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