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A multi-centric double blind homoeopathic pathogenetic trial of *Hygrophila spinosa*

G. Rakshit, A. K. Vichitra[1], P. K. Chandra[2], Rajpal[3], Vinay Kr. Singh[3], S. K. Choudhury

Drug Proving Unit (Homoeopathy), Bhubaneswar, Odisha, [1]Central Research Institute (Homoeopathy), Noida, Uttar Pradesh, [2]Dr. Anjali Chatterjee Regional Research Institute (Homoeopathy), Kolkata, West Bengal., [3]Central Council for Research in Homoeopathy, New Delhi, India

Address for correspondence:
Dr. Goutam Rakshit,
Officer-In-Charge,
Regional Research Institute (H),
Puri, Odisha - 752 001, India.
E-mail: drsujatamd@gmail.com

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ABSTRACT

Objective: The study was conducted to elicit the pathogenetic response of *Hygrophila spinosa* in homoeopathic potencies on healthy human volunteers.
Methodology: The drug *Hygrophila spinosa* was proved by the Central Council for Research in Homoeopathy (CCRH) through randomized, double-blind, placebo-controlled method. The proving was conducted at three centres viz. Central Research Institute (H), [CRI (H)] Noida, Drug Proving Unit [DPU], Bhubaneswar and Regional Research Institute (H) [RRI (H)], Kolkata. The drug was proved in two potencies (6C and 30C) on 48 apparently healthy volunteers who were selected after conducting pre-trial medical examinations by the medical specialists and routine laboratory investigations. 32 of them where kept on interventional drug trial and remaining took placebo. At CRI (H), NOIDA, 56 dose schedule (i.e. 56 doses of drug/placebo were consumed in each batch) was followed while at DPU, Bhubaneswar and at RRI (H), Kolkata, 12 dose schedule (i.e. 12 doses of drug/placebo were to be consumed in each batch) was followed. The symptoms generated during the trial period were noted by the volunteers and elaborated by the Proving Masters which were compiled at Homoeopathic Drug Proving-cum-Data Processing cell of CCRH headquarters after decoding.
Results: Out of 32 provers who were on interventional drug trial, only 14 manifested symptoms. The drug was able to produce symptoms in both the potencies. 92 symptoms appeared during the drug trial from various locations.
Conclusion: The drug pathogenesis evolved indicates its therapeutic use for urticaria, frontal sinusitis, conjunctivitis, stomatitis, gastroenteritis, nausea (morning sickness), intermittent fever etc.

Keywords: Homoeopathy, Homoeopathic pathogenetic trial, Drug proving, Hygrophila spinosa, Pathogenetic effects

INTRODUCTION

The role of traditional medicines in the treatment of various health problems is invaluable. Medicinal plants are known to provide valuable therapeutic agents, in both modern and traditional medicine. With the associated side effects of modern medicine, traditional medicines are gaining attention and are now being studied to find the scientific basis of their therapeutic actions.[1]

Medicinal and aromatic plants constitute a major segment of the flora, which provides raw materials for use in the pharmaceuticals, cosmetics, and drug industries. The age-old indigenous systems of medicines make use of many medicinal herbs. In

one of the study of the World Health Organization, it is estimated that 80 per cent of the population of developing countries relies on traditional plant based medicines for their health requirements

Hygrophila spinosa is described in ayurvedic literature as Ikshura, Ikshugandha, and Kokilasha, which means "having eyes like Kokila or the Indian cuckoo". The medicinal value of *Hygrophila spinosa* can be appreciated from the fact that the plant contains terpenoids, alkaloids, flavonoids, and is traditionally known as an aphrodisiac, renal tonic and for its health-promoting properties.[1]

The plant has been studied for haematopoeitic, antitumor, anti-inflammatory, antipyretic, hepatoprotective, diuretic, antidiabetic, antihelmithic, antibacterial, analgesic, antimotility and antioxidant etc. The pharmacologic studies of Hygrophila spinosa indicate the immense potential of this plant in the treatment of diarrhea; inflammatory ailments, including liver and kidney disorders, as well as microbial & bacterial infections, cancer and others. The studies also indicate that the plant has an important antioxidant activity due to the presence of water-soluble compounds with potent free radical-scavenging effects. Therefore, because of all these properties of the drug, an extensive investigation on clinical efficacy of the drug is needed to explore its therapeutic utility.[1]

The parts of this plant are widely used in traditional medicine for the treatment of various disorders which include anasaraca, diseases of the genito-urinary tract, vesical calculi, painful micturition, dropsy from chronic renal disease, excessive thirst, flatulence, diarrhoea, dysentery, menorrhagia, leucorrhoea, gonorrhoea, asthma, blood diseases, inflammation, cancer and rheumatism. It is also experimentally proved to possess variety of pharmacologic actions which indicate its usefulness in the treatment of different types of diseases and disorders.[1]

It produces small red pimples and eruptions which look like measles and eruptions due to prickly heat. In some skin diseases, which are worse from heat and better from cold, its efficacy is surely found. In malarial attacks associated with urticaria it is used with great benefit. These fevers appear in the morning, there is no chill or thirst, urticaria-like eruptions come on along with the rise of temperature and there is intense itching which is relieved by cold application. It is an excellent medicine in dropsy, gonorrhoea, hepatic obstruction, rheumatism and genito-urinary affections like calculus. It has a wonderful action over insomnia; it is a sure and unfailing remedy to produce sleep.[2] Thus, Central Council for Research in Homoeopathy took up the systematic Homoeopathic Drug Proving of *Hygrophila spinosa* which has important medicinal values and benefits to elaborate its therapeutic use in Homoeopathy.

Botanical name : Hygrophila auriculata (Schum.) Heine
Synonym : Hygrophila spinosa T. Anders.
Asteracantha longifolia (L.) Nees
Family : Acanthaceae

Common name:

Bengali	:	Kuliakhara
Sanskrit	:	Ikshugandha, Kokilaksha
Hindi	:	Talimkhana
Tamil	:	Nirmulli, Kazhudhai Mullu

Description

Hygrophila spinosa syn. *Hygrophila auriculata* (Schum.) is a herb growing in wet places. A stout herb; stems fasciculate, subquadrangular, erect, 0.6-1.5 m tall, thickened at the nodes, hispid with long hairs; with axillary spines, leaves 9X1 cm, hairy, oblanceolate, in whorls; flowers 2-3 cm long, purple-blue, bilabiate, in whorls; fruits capsule, 8 mm long, 4-8 seeded.[1]

Distribution

The herb is common in moist places - on the banks of tanks, ditches, and paddy fields. It is believed to be indigenous to India from the Himalayas to Srilanka, Myanmar, Malaysia, and Nepal.[1]

Objective

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

MATERIAL AND METHODS

Study design

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

Parts used in Homoeopathy

Whole fresh plant and root[2]

Potencies used in the trial

6C and 30C

Participants and setting

The Homeopathic Pathogenetic trial was conducted at three centers i.e. Central Research Institute (H)

[CRI (H)], Noida (Uttar Pradesh), Regional Research Institute (H) [RRI (H)], Kolkata (West Bengal) and Drug Proving Unit [DPU], Bhubaneswar (Odisha) during the year 2010-11. Total 48 apparently healthy volunteers from above mentioned three centers, between the age group 18 to 32 years, comprising 15 males and 33 females were included in the Homeopathic Pathogenetic trial. Pregnant and lactating mothers were excluded. Before enrolling the volunteers as provers, all of them were screened strictly by the experts.

'Written informed consent' from each volunteer was obtained before starting the trial. 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, Radiologists and their routine laboratory investigations at the centers to ascertain their health status. After recommendation of experts, healthy volunteers were enrolled in the Homeopathic Pathogenetic trial Programme. The sample size included 30% provers under control group at each center. So, out of 48 provers, 32 were kept on drug (verum) and 16 were on placebo (control) in all three batches i.e. placebo, 6C and 30C potency. All the provers were assigned code numbers and the coded drugs in 6C, 30C potencies and placebo were supplied in separate glass phials bearing code numbers of the respective volunteers; keeping both provers and proving masters blind. In addition a glass phial containing antidote was also kept with each batch.

Interventional Drug

Hygrophila spinosa was procured in 6C and 30C potencies in sealed bottles from licensed manufacturer of Homoeopathic medicines. Globules (number 30) were medicated with these attenuations at the Council's headquarters office and sent to Drug Proving Research Units in coded phial in 6C and 30C potency.

Placebo

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

Methodology of Proving

The proving of *Hygrophila spinosa* was conducted following two different dosage schedules as per Drug Proving Protocol. 56 dose schedule[3] was adhered to at CRI (H), Noida while 12 dose schedule[4] was followed at RRI (H), Kolkata and DPU, Bhubaneswar.

The study consisted of three phases. In each phase, [56 doses at CRI Noida or 12 doses at Kolkata and Bhubnaeswar] drug or placebo were administered, divided into 4 doses per day for fourteen days or three days.

Phase-I: Placebo phase. It is useful in generating prover's response to placebo and therefore symptoms generated by the prover in this stage act as control (intra prover) for subsequent phases.
Phase-II: In 2nd phase, the proving was conducted with 6C potency of the drug and during this phase 30% provers consumed placebo only.
Phase-III: In 3rd phase, the proving was conducted with 30C potency of the drug and during this phase 30% provers consumed placebo only.

Dose schedule: The provers were instructed to take 4-6 globules of a particular batch of the coded drug, four times a day, dry on tongue. Provers were instructed to note down the details of their feelings/ changes in mind and body on daily basis, after taking the coded drug/placebo in 'Prover's Day Book Proforma'.

If no sign(s)/ symptoms(s) appeared, provers noted down as 'No Symptom' with date and time of intake of the respective dose of the drug/placebo.

If sign(s)/ symptoms(s) appeared, provers were asked to stop taking the coded drug as soon as he/she felt any change or any sign(s) and/or symptoms(s) developed during the trial. The prover noted down the sequence of the appearance of new sign(s) and/ or symptoms(s), their progress and the number of doses after which such sign(s) and/or symptoms(s) appeared, with date, time of onset and duration for which they persisted. Any change in normal routine of the prover in respect of daily habits pertaining to diet, living conditions etc./any treatment taken were also noted in the Prover's Day Book Proforma. Intake of drug remained suspended till the sign(s) and/or symptoms(s) totally disappeared.

After disappearance of sign(s) and/or symptom(s) produced by the drug, the volunteer had to wait further for a period of 07 days before taking the remaining doses of that batch 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 till all the 56 doses were consumed. If the prover was experiencing the same symptom(s) what he/she had already shown, he/she was asked to stop that particular batch and to switch over to the next batch after a washout period of 14 days (symptom free period between two phases of drug proving in which a volunteer does not take drug).

In case of 12 dose schedule, volunteer has to take 4 doses per day for 3 days. If symptoms appear, he/she had to stop further intake of drug from that batch and had to switch over to next batch after 30 days washout period after disappearance of symptom(s)/ sign(s).

Each volunteer was interrogated by the Proving Master to verify the sign(s) and/or symptom(s) recorded by the volunteer in respect to location(s), sensation(s), modalities and concomitants, extension of symptoms, causation, clinico-pathological findings and other treatment taken, if any, in 'Symptoms Elaboration Proforma'.

During the course of trial, the volunteers were referred for specific laboratory investigations to rule out any other cause of appearance of new sign(s) and/or symptom(s). The opinion of the specialists (Honorary consultants) was also obtained, wherever needed.

After completion of trial of three phases, the provers underwent Terminal Medical Examination. On completion of all the respective phases of the pathogenetic trial programme, the compilation of data recorded in 'Prover's Day Book Proforma', 'Symptoms Elaboration Proforma', 'Pathological Report Sheets' and 'Terminal Medical Examination sheets', were made at the Council's headquarters by the Homoeopathic Drug Proving-cum-Data Processing Cell. After decoding, the sign(s) and/ or symptom(s) produced by the provers kept on the interventional drug were separated from those produced by the provers kept on placebo. The sign and/or symptom, which were common to both the groups, were not taken into consideration while compiling the symptomatology of the proved verum.

Management of adverse effects

A vial of antidote was sent with each quota to each center. In this trial *Camphora* 6C was used as Antidote as it is believed that Camphora can antidote nearly every vegetable medicine.[5] The Proving Master gives antidote to the prover if symptoms continue for a long time or intensity is much to cause discomfort. Proving Master is also directed to take advice of honorary consultants and to get laboratory investigations done, if required.

Pathogenetic effects

Pathogenetic effects (trial symptoms) are defined as all changes in clinical events and laboratory findings reported by the volunteers during a Homoeopathic Pathogenetic Trial 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.[6]

Pathogenetic effects were deduced from:

- Comparison of symptoms developed in placebo phase with symptoms during intervention phases (intra-prover comparison)
- Comparison of symptoms developed by the provers on control (for all for phase) with provers on actual verum trial (inter-prover comparison).

RESULTS

At Central Research Institute (H), Noida out of 18 provers, 10 provers reported symptoms. At Drug Proving Unit (H), Bhubaneswar out of 15 provers, 04 provers reported symptoms while at the same time at Regional Research Institute (H), Kolkata, out of 15 provers, none of them reported any symptom. Thus, out of 32 provers who were on interventional drug group only, 14 volunteers reported symptoms. Among these, 55 symptoms were produced during 2nd phase i.e. by 6C and 38 symptoms were produced during 3rd phase i.e. by 30C. The incidence in this Homoeopathic Drug Proving trial was 1.72 for 6C potency and 1.19 for 30C potency. In 56 dose schedule, 80 symptoms appeared as against 12 symptoms in 12 dose schedule [Tables 1 and 2].

DISCUSSION

In the present Homoeopathic Pathogenetic Trial of *Hygrophila spinosa*, 92 symptoms appeared in 14 provers. Character of pain in various symptoms was 'burning' which can be considered as key symptom of this drug. The maximum number of symptoms were observed with 56 dose schedule and only 12 symptoms were observed with 12 dose schedule. More provers developed symptoms in 56 dose schedule. There is need to work out effective dose schedule in order to get optimum drug response.

Table 1: Symptoms produced following 56 dose schedule

Location	Symptoms observed	No. of provers	Potency	Doses	Duration (in days)
Mind	Anxiety, *agg*. evening.	1	6C	56	1
Vertigo	Vertigo, *agg*. looking upward, food intake, carriage riding; *amel*. cold drink. It is accompanied with nausea, increased thirst for small quantity at a time, weakness, dullness and decreased appetite.	1	30C	56	1
Head	Heaviness in occipital region, *agg*. pressure, walking; *amel*. open air. It is accompanied with irritability, decreased thirst and pain in right shoulder and decreased appetite.	1	6C	44	2
	Headache with heaviness.	1	30C	24	1
	Headache, dullness in whole head, *agg*. noise; *amel*. pressure. It is accompanied with nausea, decreased thirst.	1	30C	14	2
	Dull, aching pain in whole head, *amel*. pressure. It is accompanied with thirstlessness.	1	6C	21	1
	Aching pain in whole head, *agg*. after rising. It is accompanied with coryza, watery nasal discharge, sneezing *agg*. morning, bodyache, pain in throat during deglutition *agg*. cold drink; *amel*. warm water, tea, no desire to drink water, restlessness, irritability.	1	30C	44	4
	Throbbing pain in whole head, *agg*. stooping, reading, talking; *amel*. cold water, pressure.	1	6C	22	1
	Aching in frontal region of head, *agg*. talking, opening eyes; *amel*. tight bandage, closing eyes. It is accompanied with heaviness in eyes.	1	6C	56	1
	Aching pain in frontal region of head, *agg*. sunlight; *amel*. pressure, sleeping. Next day, same symptom with heaviness in head, *agg*. morning.	1	6C	21	2
	Aching pain in frontal and temporal regions of head, *agg*. standing; *amel*. pressure, lying down. It is accompanied with anxiety, drowsiness, decreased thirst and low BP (100/60 mm Hg).	1	6C	56	1
	Aching pain in frontal and temporal regions of head, *amel*. pressing, lying down. It is accompanied with vertigo on rising from bed; weakness and drowsiness; pain in both eye with redness; increased thirst for cold water; loose stool; yellow in color only once in the morning.	1	6C	12	1
	Aching pain in frontal region of head, *agg*. light; *amel*. pressure. It is accompanied with nausea. Next day, same symptom with vomiting and loose stool with thirstlessness. On 3rd day, same symptom with dullness. On 4th day, headache with heaviness in whole head, *agg*. morning. It was accompanied with nausea, loose stool and decreased thirst.	1	6C	56	4
	Dull frontal headache. It is accompanied with nausea. Next day, same symptom with constipation, hard stool.	1	30C	38	2
	Stabbing pain in right temporal region. It is accompanied with watering and redness in both eyes. Next day, stabbing pain in frontal and both temporal regions.	1	6C	13	2
	Pressing pain in temples, *agg*. evening; *amel*. closing eyes. It is accompanied with disturbed sleep, restlessness and decreased appetite.	1	30C	44	2
	Aching pain in temporal region of head, *amel*. pressure, lying down. It is accompanied with heaviness in whole head.	1	30C	12	1
	Falling of hair with dandruff. It is accompanied with heaviness of head.	1	30C	42	3
Ear	Pricking pain in right ear, *agg*. talking, chewing, open air, cold air; *amel*. lying on painful side, covering.	1	30C	15	1
Eye	Heaviness and burning sensation in eyes, *amel*. cold water. It is accompanied with decreased appetite.	1	6C	56	1
	Redness of right eye, watery eyes, *agg*lutination and swelling ; pain on movement of eyeballs, *agg*. evening. On 5th day right eye get better and swelling appeared in left eye.	1	6C	40	13
	Redness, itching, swelling with aching pain in eyes, *amel*. lying down, closing eyes. Next day, same symptom swelling of eyes, *amel*. lying down. It is accompanied with increased thirst, loose stool, desire for cold drink and sweet.	1	6C	12	3

Cond...

Table 1: Contd...

Location	Symptoms observed	No. of provers	Potency	Doses	Duration (in days)
	Swelling on the eyes with aching, redness, *agg*. morning. It is accompanied with frontal headache, aching, *amel*. pressure, increased thirst, desire for cold drink. Next day, same symptom with sticky, watery discharge from eye, swelling of both upper and lower eye lids and itching in eyes. Pain, *agg*. on blinking the eyes. It is accompanied with increased thirst for cold water, irritability and no desire to talk.	1	6C	16	9
Nose	Burning sensation in nose.	1	30C	12	1
	Obstruction of nose, alternate obstruction of nostrils with difficulty in breathing, *agg*. lying down; *amel*. raising head on a level with pillows. Watery nasal discharge from left nostril. It is accompanied with desire for cold drink.	1	6C	28	1
	Sneezing with watery nasal discharge. It is accompanied with frontal headache, fever, drowsiness, weakness, increased thirst, loose stool, pain in throat with dry cough.	1	6C	36	3
	Coryza with yellow nasal discharge. It is accompanied with itching in left ear, headache in left side. Next day, same symptom with headache, bodyache, nausea, dry cough, dryness of throat and increased thirst. On 3rd day same symptom with cough with yellow expectoration. On 4th day, stuffed nose, no discharge with headache and falling of hair.	1	6C	20	4
	Coryza, obstruction in nose with difficulty in breathing, thick white mucous discharge with difficulty in clearing, coming out in strings. It is accompanied with stuffed sensation in cheeks. Next day, same symptom with increased breathing problem at night. Discharge became yellowish-white with crusting of the nose from inside and itching.	1	30C	42	3
	Coryza with thick yellowish discharge from right nostril. Next day, same symptom with obstruction of left nostril with fever. On 3rd day, discharge from left nostril with blockage of right nostril. On 4th day, thick white nasal discharge. Later on 7th day, obstruction of nose with hoarseness.	1	30C	28	9
Face	Eruption on face, painful eruption, no discharge with itching, *agg*. touch; *amel*. cold water. It is accompanied with thirstlessness, unsatisfactory offensive stool. Next day, same symptom with loss of appetite. On 3rd day, eruption left black spot on face.	1	6C	56	5
	Hard skin eruption on forehead, intensive pain to touch and press on the eruption, *agg*. pressure. Pustular eruption on upper lip of left side, filled with white material with pain on touch.	1	30C	24	2
Mouth	Aphthous ulcers and burning sensation in mouth, *agg*. eating sweets. It is accompanied with increased thirst with desire to drink in sips to relieve burning pain and desire for spicy food. Next day, same symptom with pain and swelling along jaw line due to ulcer in mouth.	1	30C	42	3
Throat	Sore throat and burning sensation in throat with desire to swallow, *agg*. afternoon. It is accompanied with feverish feeling and every breath feels fire. Next day, aching pain in throat with sneezing and watery nasal discharge, *agg*. change of air. Pain radiating to left ear. On 3rd day, same symptom with watery discharge left nostril.	1	6C	28	4
	Burning sensation in throat.	1	30C	28	1
Stomach	Nausea, *agg*. riding in carriage, eating, drinking; *amel*. open air. It is accompanied with thirstlessness and decreased appetite.	1	6C	37	1
	Nausea with vomiting of undigested things. It is accompanied with mild pain in abdomen and decreased appetite.	1	6C	21	1
	Nausea, *agg*. morning, daytime. It is accompanied with decreased thirst, burning in urination, constipation (no urge for stool) and pain in abdomen. On 3rd day, same symptom with passage of hard stool.	1	6C	41	3
	Aching pain in abdomen with all gone sensation.	1	6C	56	1
	Decreased appetite with thirstlessness.	1	6C	56	1
	Thirstlessness. Next day thirstlessness with mild nausea in morning.	1	30C	14	2
	All gone sensation. It is accompanied with decreased thirst.	1	30C	53	1

Cond...

Table 1: Contd...

Location	Symptoms observed	No. of provers	Potency	Doses	Duration (in days)
Abdomen	Aching pain in abdomen below umbilicus, *agg*. touch, lying, eating, night; *amel*. walking slowly. (O/E tenderness)	1	6C	56	1
	Aching pain in abdomen, *agg*. pressure; *amel*. walking. It is accompanied with dryness of mouth, no desire to drink.	1	6C	56	1
	Aching pain in whole abdomen, *agg*. movement; *amel*. passing stool.	1	6C	28	1
	Flatulence and eructation with thirstlessness.	1	6C	22	1
	Aching pain in abdomen. It is accompanied with loose, offensive stool and no thirst.	1	6C	21	1
	Aching pain in whole abdomen. It is accompanied with constipation, nausea *amel*. vomiting in evening, decreased thirst and appetite and disturbed sleep at night.	1	6C	41	1
	Flatulence with distension of abdomen.	1	30C	8	1
	Flatulence with distension and discomfort in abdomen, *agg*. eating; *amel*. evening, after passing stool.	1	30C	24	2
	Aching pain in abdomen with flatulence, *agg*. morning. Pain *amel*. evening. Flatulence *agg*. evening. Next day aching pain in abdomen with soft stool, *agg*. while passing stool.	1	30C	44	2
Rectum	Constipation, hard, unsatisfactory stool in small quantity. It is accompanied with heaviness in abdomen.	1	30C	12	2
	Constipation, no desire for stool. It is accompanied with thirstlessness, pain in right hypochondrium, *agg*. after eating, forward bending, sitting; *amel*. lying, standing, sitting straight. Flatulence and eructations, *agg*. morning. On 3rd day, ineffectual urging for stool (2 times), passed small quantity of offensive, brown stool. It is accompanied with flatulence with eructations. On 4th day, again there was no desire for stool with itching anus at night. On 5th day, painful evacuation of stool but in small quantity, soft, offensive. It is accompanied with burning in anus after stool, flatulence and eructations.	1	6C	22	5
	Diarrhea with loose, offensive stool, *agg*. morning. It is accompanied with pain in abdomen.	1	6C	56	1
	Diarrhea, loose stools, non offensive. It is accompanied with pain in lower abdomen during stool and weakness.	1	6C	11	7
	Loose watery stool, *agg*. morning. It was accompanied with pain in abdomen and loss of appetite.	1	6C	56	1
	Diarrhea, yellow, offensive, loose stool. It is accompanied with cutting pain in abdomen during passing stool, no desire to eat, increased thirst.	1	30C	28	3
	Diarrhea, loose offensive stool, *agg*. night. It is accompanied with pain in upper abdomen, *amel*. bending double. On 3rd day, same symptom with pain in whole abdomen, *agg*. after eating; *amel*. bending double. Also there was flatulence, bloated abdomen.	1	30C	24	3
Larynx and Trachea	Hoarseness of voice.	1	30C	28	2
Cough	Cough with white sputum, *agg*. night, morning, cold drink; *amel*. warm thing. It is accompanied with pain in throat, decreased thirst, increased appetite, drowsiness and bodyache. Later sputum became yellowish in color.	1	6C	36	10
Chest	Aching pain in mid-sternal region of chest, *agg*. evening; *amel*. passing flatus. It is accompanied with flatulence, disturbed sleep.	1	30C	53	1
Back	Aching pain with stiffness in back of neck, *agg*. motion. Pain extending to right shoulder.	1	30C	27	2
	Pustular eruption filled with pus on symphysis pubis area, painful to touch.	1	30C	44	1
Extremities	Aching pain in calf muscles, *amel*. pressure.	1	6C	39	1
	Aching pain in lower limbs, *agg*. walking; *amel*. tight bandage.	1	6C	37	1
	Aching, increased frequency of urination (9-10 times during daytime and 1-2 times in night).	1	6C	16	1

Cond...

Table 1: Contd...

Location	Symptoms observed	No. of provers	Potency	Doses	Duration (in days)
	Aching pain in right shoulder joint, *agg*. moving, touch. It is accompanied with headache and vertigo on suddenly standing from sitting. Next day, same symptom with stiffness in shoulder. On 3rd day, same symptom, *agg*. movement, lying; *amel*. oil message, sitting. On 4th day, same symptom with mild headache.	1	6C	32	4
	Eruption on lateral aspect of left thigh with pain to touch.	1	30C	24	2
	Eruption with itching and burning sensation in legs with dryness, *agg*. night, lying down, covering.	1	30C	28	5
	Aching pain in leg below knee to ankle, *agg*. walking, standing; *amel*. bandaging, covering.	1	30C	42	3
Fever	Fever with chill, intermittent type of fever, *agg*. evening. It is accompanied with decreased thirst, bodyache, headache, sleeplessness, no desire to work and dullness.	1	6C	52	8
	Fever, intensive heat and no sweating, *agg*. afternoon. Next day, same symptom with fever with weakness as if someone crushed the body. On 3rd day, fever with desire for cold drink and weakness. On 4th day, fever with marked weakness and breathlessness on movement.	1	6C	28	6
	Feverish feeling accompanied with frontal headache, leg pain, increased thirst, desire for cold milk, bodyache and disturbed sleep.	1	6C	36	1
	Fever accompanied with bodyache, headache, severe pain in left ankle and knee.	1	6C	13	3
	Fever with chills in the morning, heat stage from afternoon till night, no sweat stage. On 3rd day, fever with no chill stage and only marked heat stage.	1	30C	28	3
Skin	Pustular eruption on forehand near elbow joint, pain to touch and redness of the surrounding skin. It is accompanied with itching of whole body, *agg*. at night; *amel*. by scratching. Next day, hard eruption on the forehead in the morning with pain to touch. On 3rd day, dark spot at erupted areas and new rosy red eruption filled with serous fluid and blood appear at shoulder and thigh. It is accompanied with a lot of flatus which causes tight abdomen from morning, *agg*. after taking meal; *amel*. passing stool. On 5th day, new eruptions on left shoulder and left side of forehead, rosy red, hard eruption, filled with blood which is painful on touch.	1	6C	28	5
	Eruption (urticarial), redness, heat and itching all over body with bruised pain of affected parts, *amel*. cold water, rest, *agg*. day time, exposure to sunlight, warm room. Later the symptom was accompanied with mental irritability.	1	6C	16	6
	Urticarial rash with pale wheals and redness, itching only on scratching with sensation of heat from inside body, *agg*. warmth; *amel*. cold application, cold air.	1	6C	46	3
	Urticarial rash with pale wheals, redness, itching on parts scratched, *agg*. warmth; *amel*. by cold application.	1	6C	46	4
	Itching, red rashes on whole body. It is accompanied with headache.	1	6C	13	4
	Mild urticarial rash on different parts of body with itching. (fasting)	1	30C	52	3
Generalities	Aching pain in the whole body with weakness and desire to sleep and get covered with blanket, *agg*. motion; *amel*. rest, pressure.	1	6C	39	1

Appearance of urticarial eruptions both at both the centres corroborated with the similar observation in small proving published in Drugs of Hindoosthan. It is quite similar to urticaria of Apis mellifica where it is better by cold application and worse from heat. More over it appeared after consuming 6C potency only and in varying doses. The drug produced intermittent type of fever with decreased thirst which has also been reported in Drugs of Hindoosthan, however there were no eruption which appeared during fever. Moreover the symptoms persisted for longer duration in 6C potency as compared to 30C potency. It can be therapeutically used for conjunctivitis on the indications of watery eyes, redness of one eye, agglutination and swelling of right eye and pain on movement of eyeballs, *agg*.

Table 2: Symptoms produced following 12 dose schedule

Location	Symptoms observed	No. of Provers	Potency (ies)	Doses	Duration (in days)
Head	Heaviness of head, *amel*. by pressure accompanied with thirstlessness.	1	6C	1	3
	Frontal headache, *amel*. pressing teeth.	1	30C	12	1
Ear	Drawing pain in left ear, *agg*. morning, evening, from exposure to cold.	1	6C	2	1
Eye	Burning sensation in eyes.	2	6C, 30C	1, 12	1
Nose	Burning sensation in nose.	1	30C	12	1
Face	Dryness of skin, left cheek, white spot of left cheek.	1	6C	2	4
Throat	Sore pain.	1	30C	12	1
Stomach	Unquenchable thirst for water.	1	30C	4	1
Extremities	Sore pain in both right and left corner (nail bed) of great toes of both feet.	1	6C	4	2
	Urticaria on medial aspect of both thighs with severe itching followed by burning sensation, red in appearance. Next day, urticaria on left arm.	1	6C	3	2
Fever	Feverish feeling with thirstlessness.	1	30C	12	1
Generalities	General weakness. Next day sore, lame, bruised sensation all over the body.	1	30C	4	2

evening. Absence of any symptoms from male and female genitalia is conspicuous. Following symptoms may also be considered as guiding symptoms:

- Diarrhoea, loose stools, non-offensive. It is accompanied with pain in lower abdomen and weakness.
- Cough with white sputum, *agg*. night, morning, cold drink; *amel*. warm thing. It is accompanied with pain in throat, decreased thirst, increased appetite, drowsiness and bodyache. Later sputum became yellowish in colour.
- Fever, intensive heat and no sweating, *agg*. afternoon with weakness as if someone crushed the body, desire for cold drink and weakness. Weakness increase markedly with fever and accompanied with breathlessness on movement.
- Aching pain in frontal and temporal regions of head, *agg*. standing; *amel*. pressure, lying down. It is accompanied with anxiety, drowsiness, decreased thirst.
- Diarrhea, loose offensive stool, *agg*. night. It is accompanied with pain in upper abdomen, *amel*. bending double.
- Thirstlessness

CONCLUSION

The drug pathogenesis evolved indicates its therapeutic use for urticaria, frontal sinusitis, conjunctivitis, stomatitis, gastroenteritis, nausea (morning sickness) intermittent fever etc. However, the medicine deserves our attention in the future and more clinical experiences should be forthcoming through further clinical verification.

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REFERENCES:

1. Available at: http://www.phcogrev.com/article.asp?issn=0973-7847;year=2010;volume=4;issue=8; spage=167;epage=171;aulast=Kshirsagar [Accessed on 2012 Aug 12].
2. Ghose SC. Drugs of Hindoosthan. Eighth edition. Hahnemann publishing co. pvt. Limited. Calcutta. p.192.
3. Protocol, homoeopathic pathogenetic trial (Drug Proving), Central Council for Research in Homoeopathy. Min. of H and FW, New Delhi; 2007.
4. Available at: http://ccrhindia.org/drugprovingintro.asp [Accessed on 2014 Mar 20].
5. Allen HC. Key notes and Characteristics with comparisons of some of the leading remedies of the Materia Medica with Bowel Nosodes. Eighth edition. B.Jain Publishers (p) Ltd. New Delhi; 2008: 78.
6. Dantas F, Fisher P, Walach H, Wieland F, Rastogi DP, Teixeira H *et al*. A systematic review of the quality of homoeopathic pathogenetic trial published from 1945 to 1995. Homoeopathy. 96 (1), 2007 Jan: 4-16.

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उद्देश्यः अध्ययन का उद्देश्य स्वस्थ्य मानव स्वंयसेवकों पर होम्योपैथिक पोटेंसी में हाइग्रोफिला स्पाइनोसा की मानव विकारी प्रतिक्रिया को प्रकाश में लाना था।

सामग्री एवं विधियाँः हाइग्रोफिला स्पाइनोसा औषधि डबल ब्लाईंड प्लासिबो नियंत्रित विधि से केन्द्रीय होम्योपैथी अनुसंधान परिषद् द्वारा प्रमाणित की गयी। अध्ययन को तीन केन्द्रो, केन्द्रीय होम्योपैथी अनुसंधान संस्थान, नोयड़ा, औषध प्रमाणन इकाई, भुवनेश्वर व क्षेत्रीय होम्योपैथिक अनुसंधान संस्थान पर आयोजित किया गया। दवाओं को दो पोटेंसियो (6सी और 30सी) में 48 स्वस्थ स्वंयसेवकों में प्रयोग किया गया जोकि चिकित्सीय विशेषज्ञों और नियमित प्रयोगशाला जाँचों द्वारा पूर्व–परीक्षण चिकित्सा परीक्षाओं के बाद चुने गये। 32 स्वयंसेवकों को हाइग्रोफिला स्पाइनोसा और 16 को प्लासिबो दी गई। नोयडा में 56 खुराकों की योजना का अनुसरण किया गया जबकि भुवनेश्वर व कोलकाता में खुराकों की योजना का अनुसरण किया गया। परीक्षण अवधि के दौरान उत्पन्न लक्षणों को स्वंयसेवकों द्वारा नोट किया गया और जाँचकर्ताओं द्वारा विस्तारित किया गया। तीनों केन्द्रों से प्राप्त आकंडों को डिकोडिंग के बाद परिषद् मुख्यालय के प्रमाणन की आंकड़ा प्रक्रिया सेल में संकलित किया गया।

परिणामः 32 प्रमाणकों में से 14 में लक्षण प्रकट हुए जो वास्तविक दवा परीक्षण पर थे। दवा शरीर के अधिकतर हिस्सों में, प्रत्येक पोटेसीं में लक्षण उत्पन्न करने में सक्षम थी।

निष्कर्षः हाइग्रोफिला स्पाइनोसा के प्रमाणन परीक्षण के दौरान नए और प्रमाणित रोगजनक प्रतिक्रियाओं से दवा का उपयोग बढ़ेगा और अनुसंधान विद्वानों एवं चिकित्सकों को लाभ होगा। यह लक्षण और अधिक मूल्यवान होगें और सत्यापित किये जायेंगे।