Saraca Indica: A Multicentric Double Blind Homoeopathic Pathogenetic Trial

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Abstract
Objective: To elicit the pharmacodynamic response of the drug Saraca Indica on healthy human beings in non-toxic doses. Methodology: Drug Saraca Indica was proved through a double-blind method. The study was conducted at 3 centers. The Homoeopathic preparation of the drug was proved in three potencies (6C, 30C and 200C) on 42 volunteers who were selected and declared apparently healthy during their pre-trial medical examination by the specialists and through their routine pathological investigation. 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. 29 provers were on actual drug trial while 13 provers were kept on placebo. 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 all the centers was compiled at proving-cum-data processing cell at Central Council for Research in Homoeopathy (CCRH) headquarters after de-coding the drug. Observations: Out of the 29 provers, who were on actual drug trial, 08 manifested symptoms. Drug was able to produce symptoms in each potency. Only one symptom appeared in more than one prover. Some of the symptoms have been reproved which are mentioned in the fragmentary provings published in different literatures. Conclusion: Pharmacodynamic responses, elicited (new and reproved) 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.

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

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Conclusion: Pharmacodynamic responses, elicited (new and reproved) 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; Saraca indica.

Introduction

Dr. D.N. Roy of Kolkata made a short proving of the drug. Though the proving was of a fragmentary character, it was an open secret that the late Dr. D.N. Roy was very fond of indigenous plants and kept them always with him for use in times of emergency. *Saraca indica* (*Asoka*) is regarded as one of the sacred plants of the Hindus. If the term *Asoka* be literally translated it will mean the 'remover of all the ailments'. The *rishis* of ancient times have written the following about this plant:

"Whoever (a female) after having an ablation, with a pure body and mind, takes eight new buds of *Asoka* on the festive day fixed and recommended, gets rid of all ailments proceeding from menstrual disorders and the despondency of such a woman from sterility soon disappears as her craving for motherhood is generally fulfilled." *Charaka* has placed it in the list of anodyne remedies. In any case, the ayurvedic physicians along with some allopathic has used and have been using it in all sorts of menstrual troubles and uterine disorders with great success and efficacy for a long time. There are many indigenous preparations pregnant with *Asoka*, such as *Asoka Cordial*, *Asoka ghrita*, *Asokarista* and
similar other preparations are available in Indian market and are in constant demand amongst the suffering humanity for all sorts of female troubles.¹

Bark contains a fair amount of tannin and catachin-(Hooper). Abbot (1887) stated that this contained haematoxylin. The alcoholic extract, which was mostly soluble in hot water, showed the presence of a fair amount of tannin and probably an organic substance containing iron. Bark is strongly astringent and uterine sedative. It acts directly on the muscular fibers of the uterus. It has a stimulating effect on endometrium and the ovarian tissue. Bark is much useful in uterine affections especially menorrhagia due to uterine fibroids and other causes.²

The bark is bitter and acid; refrigerant, astringent to the bowels, alexiteric, anthelmintic, demulcent, emollient; cures dyspepsia, thirst, burning sensation, diseases of the blood, biliousness, effects of fatigue, tumors, enlargement of the abdomen, colic, piles, ulcers, bloody discharges from the uterus, menorrhagia; useful in fractures of the bones; beautifies the complexion. The seeds are useful in urinary discharges (Ayurveda). The drug is also used in scorpion-sting.³

Objective

To elicit the pharmacodynamic response of the drug Saraca indica on apparently healthy human volunteers, in non-toxic doses.

Literature review²

Botanical name : Saraca indica Linn.
Natural Order : Caesalpiniaceae
Common names:
English : Asoka Tree
Hindi & Bengai : Anganapriya
Sanskrit : Asoka; Kankeli
Uritya : Asoka
Gujrati : Ashopalava

Description

A tree 6-9 m. high; branches glabrous. Leaves 15-25 cm. long; rhachis glabrous, coryx at the base; petioles very short; stipules intrapetiolar, completely united, 10-13 by 6 mm., scarious, ovate-oblong, obtuse, parallel-nerved. Leaflets 4-6 pairs, 10-20 cm by 3-5.7 cm., oblong-lanceolate, obtuse or acute, quite glabrous, base rounded or cuneate, slightly oblique; petiolules 4.5-6.5 mm. long, stout, wrinkled, stipels deciduous. Flowers fragrant, numerous, in dense axillary corymbs, 7.5-10 cm. across; peduncels stout; pedicels 8-13 mm. long, red, glabrous; bracts ovate, subacute; bracteoles 2, appearing like a calyx, 4mm. long; spatulate oblong, sub-acute, ciliolate, amplexicaul, coloured. Calyx passing from yellow to orange and finally red; tube 1.3-2 cm. long, cylindric, solid at the base; segments 4, oblong or obovate-oblong, 1 cm. long. Petals 0. Stamens 7 or 8, much exerted; filaments filiform, thrice as long as the calyx-segments; anthers purple. Ovary pubescent, especially on the sutures; style curved into a ring. Pod black, 10-25 by 4.5-5 cm., linear-oblong, tapering at both ends, compressed, glabrous, veined. Seeds 4-8, ellipsoid-oblong, 3.8 cm. long, slightly compressed.³

Distribution

Cultivated in gardens throughout India for its handsome flowers.² Central and E. Himalaya, E. Bengal, Burma, W. Peninsula, Ceylon-Malaya.³⁴

Parts used in Homoeopathy

Bark and fruit ¹

Materials and Methods

Location and duration of study

The proving was conducted at Drug Proving Research Unit (H) Ghaziabad, in 2003-04; at Drug Proving Research Unit (H), Midnapore and at Regional Research Institute (H), New Delhi in 2004-05.

Participants

Total 42 apparently healthy volunteers from above mentioned 3 centers, between the age group of 18 to 50 years, comprising of 31 males and 11 females, were enrolled in 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, Radiologists and their routine laboratory investigations at all three centers to ascertain their health status.

Drug

*Saraca indica* was procured in 6C, 30C and 200C potencies 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 headquarters office and sent to Drug Proving Units/Institutes in coded phials (verum) along with placebo (control).

Placebo

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

Study Design

The study was a randomized double blind placebo controlled trial.

Methods

Before commencing the study, all provers were screened strictly on the basis of Inclusion and Exclusion criteria of “drug proving protocol” of CCRH.

Inclusion criteria includes

1. The prover must be between 18-50 years of age, both males and females.

2. The provers should be apparently healthy. He/she should not show severe psychic or physical symptoms need any kind of medical treatment. Pre-trial Medical Examination (PME) should confirm healthy status of the prover.

3. The prover must be intelligent enough to record the subjective symptoms generated by the drug during proving. Facts must be recorded very carefully.

Exclusive criteria includes

1. Persons suffering from any chronic disease and under any kind of medical treatment.

2. Hysterical or anxious persons as such individuals display a high incidence of ‘Placebo effects’.

3. Those who suffer from hypersensitivity diseases such as asthma, allergies, food hypersensitivities.

4. Pregnancy, puerperium, breast-feeding.

5. Colour blindness.

6. Age of less than 18 years.

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. The study was conducted at 3 centers. According to CCRH Drug Proving Protocol, the sample size should included 30% control at each center. So, out of 42 volunteers, 31 were kept on drug (verum) and 11 were on placebo (control). All the volunteers were assigned code numbers and the coded drugs of different potencies (including placebo) were supplied in separate glass phials bearing code numbers of the respective volunteers; keeping both provers and proving masters blind about what provers are consuming (drug or placebo).

The study consisted of four stages of which first was pre-trial observation (run-in) period with placebo and after that subsequent three different potencies viz. 200C, 30C and6C. Each potency of the drug was given in 56 doses. The drug/placebo was taken by the volunteers as 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. There is also a column for any change in normal routine of the Prover in respect of daily habits pertaining to diet, living conditions etc./Any treatment taken in the Prover’s Day Book Proforma.
If the Prover is experiencing the same symptoms what he/she has already shown, he/she is asked to stop the current quota and to switch over to the next quota after a washout period of 14 days.

Management of adverse effects – A vial of antidote is sent with each quota to each center. Proving master gives antidote to the volunteer if any adverse effect is seen in the prover. Proving Master is also directed to take advice of honorary consultants and to get laboratory investigations done if required.

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 reappearance 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.

Each Prover was interrogated everyday by Proving Master about the appearance of new symptoms or progress of symptoms and noted it in ‘Symptom Elaboration Proforma’ w.r.t. Appearance and disappearance of symptoms, Location, sensation/character, Modalities, Concomitants, Extension/Direction Radiation of symptoms, Causation, Clinico-pathological findings, Remarks/other treatment taken.

- If no sign(s)/symptoms(s) appeared:

If no symptom was observed, 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 (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 identify any 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.

Pathogenetic effects

Pathogenetic effects (Proving symptoms) are defined as all changes in clinical events and laboratory findings reported by volunteers during an HPT and recorded in the final report. The incidence of pathogenetic effects per volunteer is defined as the total number of findings claimed in the trial divided by the total number of subjects. So incidence in this proving was 3.75 findings per volunteer.

The criteria for selection of pathogenetic effects was both intraprove (i.e. pathogenetic effects produced by prover in 1st run-in pre-trial observation period with placebo and in subsequent stages on verum) and interprover (i.e. comparison of pathogenetic effects produced in provers on verum with provers who remained throughout on placebo).

Results

At Drug Proving Research Unit (DPRU), Ghaziabad out of 15 volunteers, two volunteers reported symptoms, Drug Proving Research Unit (DPRU), Midnapore out of 17 volunteers, six volunteers reported symptoms and in Regional Research Institute (RRI), New Delhi out of 10 volunteers, no 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 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.

Vertigo

- **Vertigo**\(^{1,5}\) in the morning with mild left sided headache (1,200C)

Head

- Severe bursting pain in whole head with high fever, dry cough and thirstlessness, agg. in the evening, by lying down (1, 30C)
- Mild left sided headache\(^{1,5,6}\) with vertigo\(^{1,5}\), agg. after rising from the bed & continues whole day, amel. after sleep (1,200C)

Throat

- Dryness of throat with dry cough (1, 30C)

Stomach

- **Nausea**\(^{1,5,6}\) with body ache & fever (1,30C)
- Nauseating sensation with acidity & headache, amel. after sleep (1,30C)
- **Increased thirst**\(^{1,5,6}\) for cold water (2,6C)
- Thirstlessness with severe bursting headache, high fever & dry cough. (1,30C)
- **No appetite**\(^{1,5}\) but thirst for cold water (1,200C)

Abdomen

- Pain in abdomen with loose yellowish stools (1, 200C)
- Pain in upper part of abdomen while coughing (1, 30C)
- Uneasy feeling in abdomen with soft stool mixed with mucus. (1, 200C)
- Gripping pain in lower abdomen with semi-solid stool in evening (1, 200C)

Stool

- Loose stools, agg. early morning with pain in abdomen (1, 200C)
- Soft stool with mucus (1, 200C)
- Frequent offensive, watery, loose stool with flatulence & profound weakness followed by semisolid stool in evening (1, 200C)
- Loose yellowish stools (1, 200C)

Urinary bladder

- Burning during & after micturition with increased thirst for cold water (1, 6C)

Urine

- Yellow urine passes in daytime & pale in evening (1,6C)

Cough

- Dry cough\(^{1,5}\) with thirstlessness & high fever. (1, 30C)
- Dry cough, amel. after drinking water (1, 30C)

Extremities

- Itching in rashes over the left leg with rashes, burning sensation after scratching. Itching in the left heel with pain & redness. (1, 6C)
- Pain in right knee joint, agg. while bending the leg; amel. by taking rest, warm water fomentation (1,6C)
- Cutting pain in right knee joint with slight swelling, agg. in morning; amel. by hot water fomentation (1,6C)
- Pain in calf muscle, knee joint, ankle joint of left leg, agg. at night, movement; amel. by pressure (1,30C)
Sleep

- Disturbed sleep\(^1,5,6\) due to pain in left leg (1, 30C)
- Disturbed sleep due to dry cough (1, 30C)

Fever

- Chilliness with thirstlessness\(^1,5\) followed by high fever & dry cough (1,30C)
- Fever with bodyache & nausea, \textit{agg.} in morning. (1,30C)

Generalities

- Profound weakness after frequent, watery, offensive, loose stool (1, 200C)

Discussion

Drug was able to produce symptoms in 6C, 30C and 200C potencies. Only one symptom \textit{viz.} Increased thirst for cold water appeared in more than one prove. Eight symptoms were reproved which are already cited in the literatures of fragmentary proving.

The drug seems to be indicated in vertigo, headache, dry cough and fever. Drug has also produced nausea, loss of appetite, loose, watery stool with flatulence and griping pain in lower abdomen. It also produces disturbed sleep due to various reasons. These symptoms may help in clinical application of the medicine.

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Conclusion

Symptoms appeared during the trial will add to the available literatures on this medicine and benefit the research scholars and clinicians. These proved symptoms need further verification through clinical application in different settings.

References