

An Indian Drug, Ocimum Sanctum - A Clinical Trial Study

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Abstract

A Prospective Experimental, randomised clinical trial was conducted at RHMC, Rajkot for a period of 6 months with a 3 – month intervention and follow up period, aiming to ascertain the Effectiveness of OCIMUM SANCTUM through a clinical trial. In this study, after Screening of patients, it is observed that the most cases were presented with Respiratory symptoms, GI symptoms, GUT symptoms and Reproductive symptoms. 30 cases completed the study in which marked improvement were seen in 50% cases, moderate improvement in 30% cases and mild improvement or no improvement is observed in 20% cases. Ocimum Sanctum offered highly significant relief to the patients suffering from Respiratory complaints markedly, followed by the GIT symptoms, GUT symptoms and Reproductive symptoms with the use of 30 CH potency. Ocimum sanctum is safe with no adverse effects. In future, studies can be done for clinical verification of Ocimum Sanctum as it is a small and lesser-known drug and there is a limitation of time duration.

Keywords: Ocimum Sanctum, Homoeopathy, Randomized clinical trial study.

Introduction

TULSI – “The queen of herbs”

Background

India is a country impregnated with a treasure of medicinal herbs which have been used since ancient era. India is a unique country of great cultural diversity and social plurality. People practice different religions, traditions, and customs. Such diversity is also visible in the practice of the medicine and its acceptance by people even though India is the seat of one of the richest ancient medical practices, many people follow homoeopathy as well.

Ocimum sanctum is a Homoeopathic Medicine which is prepared by TULSI. It is arguably one of the most important plants in India. It is of both religious and medicinal value and is found to grow well in moist soil. The flowers, seeds, leaves and oil of the tulsi plant are used for treating different diseases. Ocimum sanctum has been recommended for the treatment of bronchitis, malaria, diarrhoea, dysentery,

skin disease, arthritis, eye disease, insect bites and so on. The ocimum sanctum also possesses anti-cancer, anti-diabetic, antifungal, antimicrobial, cardioprotective, analgesic, antispasmodic actions.

Research Question

Whether the patients will get beneficial results after prescribing ocimum sanctum?

Hypothesis

Null Hypothesis: - There will be no improvement after prescribing ocimum sanctum.

Alternative Hypothesis: - There will be improvement in the patients after prescribing ocimum sanctum.

Justification

Homoeopathy, which was introduced in India approximately two centuries ago, is an important component of India's pluralistic health care system. Homoeopathy is a rational therapeutic system with the aim of curing the sufferings of a person by administration of drugs which have been experimentally proved on healthy human beings and have capacity to produce similar sufferings. Homoeopathy is based on nature's law of cure. Homoeopathy treats the patient and not the disease.

Ocimum sanctum is a plant that is native to India. The Ocimum sanctum is useful in many varieties of disease condition and the crude material for the preparation of this medicine is easily available in India. The medicine prepared by using the indigenous material has extraordinary quality. As India – the motherland; rich in many forest and mineral resources inhabitants of this country are being disregarded as they failed to evaluate their indigenous herbs under the influence of western drugs. Now is the time to have careful look into our indigenous medicines for maximum benefit. The purpose of choosing this topic is to spread awareness about Indian medicinal herbs in the society and treat the patients by using the holy medicine which has no side effects. Lesser-known homoeopathic medicines are of great value where the complete totality of patient is not available. So, these drugs are highly suitable for the conditions where the time is short, and judgement is difficult.

Review of Literature

Botanical name: Ocimum Sanctum

Family: Lamiaceae

Synonyms: Sanskrit-Bishnu-priya; English-Holy Basil. Hindi- Tulsi



Description of the plant ^{1,2}

It is a well-known herb in India. It is a highly sweet-scented plant and is considered by the natives of India to be of great value. Its greatest importance to the Hindus is felt in connection with all their religious ceremonies. There is a story current in the Hindu mythology that Bindu, wife of Sankhachura, was favoured by Krishna and transformed into this herb. It is, therefore, regarded by all Hindus, especially by those belonging to the Vaishnava sect to be a very sacred plant. Every Hindu house in India possesses at least one plant which is looked upon by the Hindu population as one of their domestic deities. The leaves of this herb form one of the principal ingredients of every kind of offering and worship. Wood is also used for all religious purposes.

It is a strongly scented herb about 1-3 feet long, erect containing opposite leaves, oval and narrowed at lower end, flowers whorled, tips of pedicles re-curved, base woody, root vertical and fibrous. The herb can be found in abundance all over India and no less than half a dozen varieties are found the black and the white qualities varieties. If it is distilled, it yields a yellowish green volatile oil, lighter than water, which solidifies in time into a crystalline camphor isometric with that of Turpentine. The leaves, when rubbed, give off a peculiar strong odour. It is acrid, sweet-scented, and calorific.

Ayurvedic uses^{1,2}

Ocimum Sanctum very efficacious in cough, cold, catarrh, nose affections, intermittent fevers, and constipation. It is demulcent, expectorant, and anti-periodic; with Kalamiri it is given in catarrhal affection of the lungs and cough. The paste of the leaves with Suntha is given in intermittent and remittent fevers. The medicated oil is used as drops into the ears in earache and in purulent discharges and into the nose in ozaena. The seeds are mucilaginous and used as a diuretic in scanty urine and cough.

Homoeopathic review: ^{3,4,5}

Dr Mure has proven and introduced this remedy into homoeopathy. Dr. Mure's experience was several times verified by several noted homoeopaths. Dr. Pramada Prasanna Biswas of Bengal, N Sinha and N. C Ghosh have made provings of this drug.

It acts on almost every system of the body. In provings it is seen that there are prominent symptoms related to Respiratory system, GIT system, GUT and Reproductive symptoms are observed.

Mind- Forgetfulness; cannot devote attention and mind to any subject. Very much disturbed, difficulty to concentrate it on any subject, there may be irregular delirium, child is peevish and cries, does not like to lie in bed; prostration and drowsiness exist; patient falls asleep while answering questions.

Head- Headache heavy, throbbing pain as if thousand nails were being driven into it, relieved by pressure. Giddiness

Eyes- Eyes red, pain in the eyes, lachrymation. Mist before eyes, especially when fixing them on something.

Ears- Noises in the ears, loud sound appears to be very painful, watery secretion from the ear, offensive pus from the ears, shortness of hearing, ears painful due to nasal catarrh.

Nose- It is an excellent remedy in nasal catarrh associated with frequent sneezing, secretions being white or yellow. Watery discharges from the nose, nostrils ulcerated, bleeding from the nose.

Face and mouth- Face red or pale with reddish hue and lips bright red, watery salivation or spitting from the mouth, putrid and bitter taste in mouth, ulcer in the mouth, aphthae in mouth; ulcer in mouth and tongue of children, the whole tongue is bright red, or its edges and sides are red and the middle portion is deeply coated; lips dry and black as if burnt.

Throat- Pain is felt in the throat, pain and difficulty in deglutition, pain felt in the throat while walking or during coughing, the redness exists inside of the throat, ulceration of throat, glairy phlegm, enlargement of both tonsils, voice gets changed, hoarseness.

Stomach and abdomen- Abdomen distended, eructations, want of appetite, hiccough; gurgling sound is felt in abdomen; heaviness in abdomen; heaviness of abdomen does not disappear despite frequent passage of stools; pain in the abdomen, may be griping; pain is felt over the region of liver and spleen; hepatic pain, pain in the right iliac region, gurgling sound can be felt on pressure.

Stools- Stools liquid, copious, watery, very offensive; yellowish or greenish liquid stools, mucous or bloody or streaked with blood. Involuntary stools during high fever; abdominal distension is not lessened despite frequent stools, distension is felt less after stool, but again returns after a few minutes; diarrhoea during rainy season and autumn.

Urine- Involuntary urination of the children; burning in the urethra while urinating; discharge of mucus with urine. Desire to urinate off and on.

Female genitalia- Discharge of lochia is very offensive and lasts for a long period, profuse bloody discharges after delivery: leucorrhoea.

Chest- Pains are felt on both sides of the chest, worse while coughing or sneezing. Patient cannot lie quietly in bed, pleuritic pains in the chest. Asthmatic attack, wheezing and rattling sound is felt in the chest (very useful in asthma of infants and children); pain is felt in the middle of sternum.

Skin- It is very useful in skin diseases.

Materials & Methods

- **Study setting-** Study was conducted on the 30 cases selected randomly from the O.P.D. of Sainath homeopathic hospital attached with the Rajkot Homeopathic College affiliated with Parul university.
- **Study duration-** 6 months
- **Sample size-** 30
- **Selection of Samples-** Samples were selected based on totality.
- **Inclusion Criteria-** Cases were included irrespective of age, sex, caste, and religion where ocimum sanctum is indicated.
- **Exclusion Criteria** - Patient who had not given written consent.
 - In the cases with severe pathological conditions

- **Informed Consent-** Written consent was taken from the patient for the study.
- **Withdrawal Criteria -**
 - If the patient is not benefitting from the treatment, then patient can withdraw.
 - If the disease is becoming worse & it is not under the control of physician, then also patient can withdraw.
 - Any patient is found to be uncooperative during the study.
 - Any subject who wishes to withdraw his / her consent for participation in the study.
- **Study Design-**
 - **Type of Method:** A Prospective, Randomized, clinical trial.
 - **Allocation:** The patients fulfilling the eligibility criteria have been enrolled on and randomization of patients included random allocation of the subjects. Patients were randomized using simple randomization technique.
 - **Primary goal:** To determine whether Homoeopathic medicine *Ocimum Sanctum* was effective in the randomly selected cases. We want to make a scientifically valid determination- i.e., want unbiased assessment of treatment effect.
- **Intervention-**
 - Medicine was dispensed from the dispensing unit of SAINATH HOMOEOPATHIC HOSPITAL ATTACHED WITH RAJKOT HOMOEOPATHIC MEDICAL COLLEGE, under the supervision of the Investigator or her designated nominee or from any licensed Homoeopathic pharmacies after detailed case taking as per case report form.
 - Packaging, labelling and re – supply: The Homoeopathic medicine OCIMUM SANCTUM was packed, labelled, and supplied by the investigator.
 - Medicine: OCIMUM SANCTUM
 - Doses: Medicine was prescribed single dose or three times a day (morning, afternoon, and evening) in the form of globules, 4 globules per time of size 40.
 - Potency: The potency - 30CH/ 200 CH
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- **Co – interventions:**
 - **Included Co-interventions.**
 - ✓ **Rescue medicines:**
 - If conditions are unbearable rescue medicines were allowed to the patients by the investigator, however; such interventions were recorded in the Case taking proforma with description of the type of intervention, dose, and duration. If medication given is in violation to the study, then such subjects were withdrawn from the trial.
 - In case of acute symptoms, acute homoeopathic remedies can be given in between.
 - ✓ **Concomitant therapy essential medicines such as antihypertensive, diabetes, etc were allowed.**
 - **Excluded Co- interventions.**
 - ✓ Stopping of mainstream interventions especially standard treatment or conventional Allopathic, Homoeopathic, Ayurvedic treatment, etc.
 - ✓ Prohibition of theoretical antidotes e.g., Medications, toiletries, foods & beverages.
- **Selection Of Tools-**
 - Case taking Proforma & Consent:** Recording of each patient's complaints was done following a standardized case taking proforma along with Consent form & patient information sheet were especially designed for the study.

• Data Collection-

All the clinical data related to the study were kept in the form of hard as well as soft copy.

- Dropped out
 - ✓ Any of the patients if met some emergency state like accident or dropped his /her registration in between or changed the mode of treatment have been reported and dropped out from the study.
 - ✓ If the patient did not report for follow up for at least 2 visits or 1 month during the treatment were dropped out.
- Attention was paid to every stage of patient's illnesses, medicines prescribed & their dispensing, for the desired level of standards.
- Patients were monitored through regular check-ups. Patient's information has been kept safe & confidential.
- Analysis & Evaluation of the symptoms was done according to Homoeopathic principles.
- The patient's record was maintained to draw the conclusion.
- Outcome Assessment-
 - ✓ The outcome assessment of treatment was assessed by symptomatic assessment.
 - Marked improvement = 76- 100 %.**
 - Moderate improvement = 51 – 75 %.**
 - Mild improvement= 26 – 50 %.**
 - No relief = < 25 % to 0% or (–) Negative.**

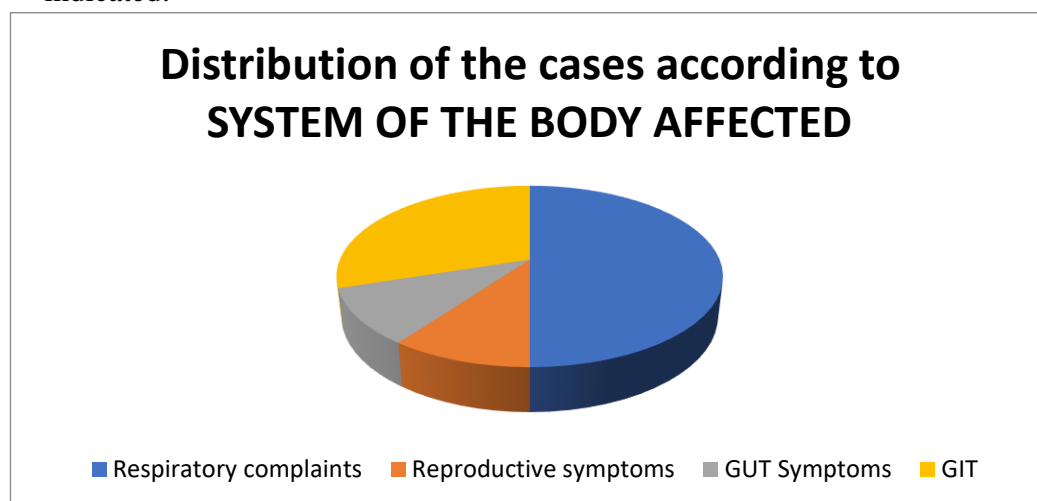
• Ethical Issues-

- Not only proved Homoeopathic medicine Ocimum Sanctum was used. No side effects had been reported with use of proved Homoeopathic medicine Ocimum sanctum.
- Informed consent was obtained from every recruited patient including adequacy of the information being provided to the subjects.
- All the evaluation forms, reports and other records related to the study were kept confidential.

Results & Discussion

The work of “An Indian Drug, Ocimum Sanctum - A Clinical Trial study” is mainly studied in reference to 30 clinical cases.

1. Distribution of the cases according to the system of the body, where Ocimum Sanctum is indicated:-

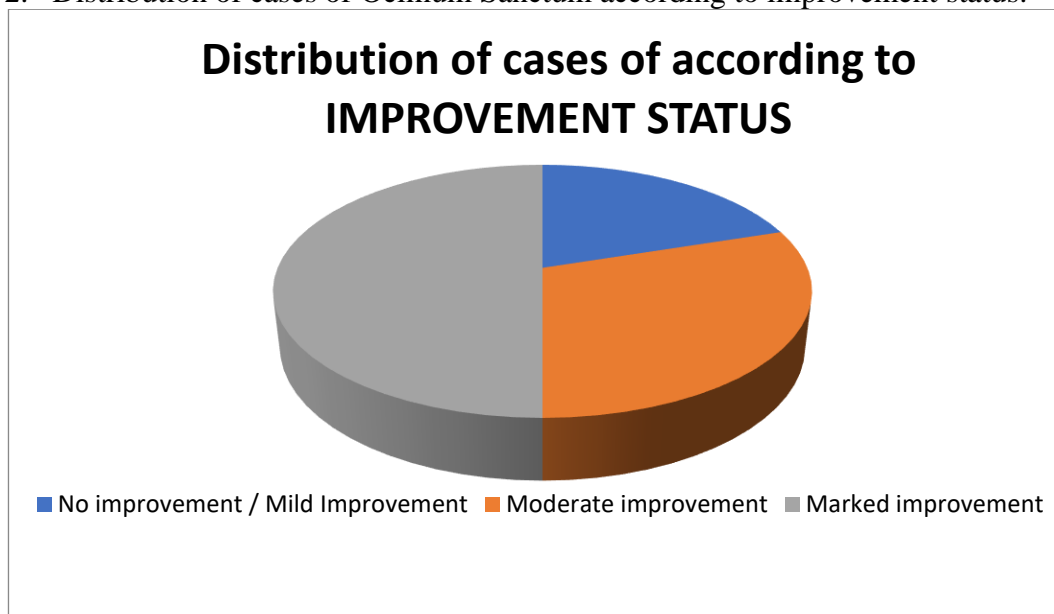


As shown in Chart 1, maximum incidence of 15 cases (50%) was observed in cases of RESPIRATORY symptoms.

Also incidence of 9 cases (30%) were observed in case of GIT.

But minimum incidences were seen in both GUT and REPRODUCTIVE system which is 3 cases each (10% each).

2. Distribution of cases of Ocimum Sanctum according to improvement status: -



As shown in chart 2, according to study done on 30 cases, it is seen that...

There was marked improvement in 50% cases.

Moderate improvement in 30% cases

Mild or no improvement in 20% cases

SUMMARY AND CONCLUSION

After intensive study on “A clinical trial to assess the effectiveness of Indian drugs with a special emphasis on OCIMUM SANCTUM”, following observations were derived:

- i. Ocimum sanctum covers mostly the cases of Respiratory illness.
- ii. It mildly covers the cases of GIT, GUT and Reproductive system.
- iii. It acts best when it is prescribed in Lower potency(30C)
- iv. 50% of cases showed marked improvement, 30% of cases showed moderate improvement and 20% shows mild to no improvement.
- v. It was mostly used in cases of cold-coryza, cough, breathlessness, pain in chest, diarrhoea, and leucorrhoea.

Thus, Homoeopathic medicine *OCIMUM SANCTUM* offered highly significant relief to patients where it is indicated. In this study, it is found that the most cases recovered were of Respiratory system followed by reproductive organs complaints and gut complaints and git complaints.

There are also certain limitations of this study. During the study, few clinical symptoms of *OCIMUM SANCTUM* were seen, that were in some patients only, as it is a small & a lesser-known drug. So, further research is required as there is paucity of sample size as well as the time duration of 6 months with follow up of was a Limitation of the study. Hence, it is advisable that further research with longer follow-up should be done on the *OCIMUM SANCTUM* medicine.

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- Dr. Alfaiz Kureshi is a PG Scholar at Rajkot Homoeopathic Medical College, Rajkot, Gujarat.

Conflicts of Interest

There is no conflict of Interest.

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