

Staphylococcinum - A multicenter clinical verification study

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Introduction: Clinical verification is an ongoing research programme of the Central Council for Research in Homoeopathy, under which many Indian and rarely used drugs in Homoeopathy have been Clinically Verified. Staphylococcinum is a nosode, prepared from the bacterial endotoxins of staphylococcus pyogenes aureus.

In India, the medicine is prepared as per the direction of preparation of nosodes of N-I group of Homoeopathic Pharmacopoeia of India (HPI). The Council had undertaken an observational study on Staphylococcinum from 2005-2010, to determine its therapeutic effects through Clinical Verification.

Objectives: The study had two objectives. The primary objective was to clinically verify the symptomatology of Staphylococcinum as observed during its proving conducted by Council on this drug and the secondary objective was to ascertain the additional clinical symptoms, if any.

Materials and Methods: In this multi-center study, a total of 411 patients from all age groups & both sexes were enrolled from the OPDs of the institutes and units of the Council adhering to the inclusion, exclusion criteria as per protocol. The informed written consent was obtained from each patient before the enrolment in the studies.

The presenting signs and symptoms were recorded in a predefined case recording proforma. On repertorising the symptoms of each patient, if Staphylococcinum was found to be the simillimum or very closely similar to the symptoms of the patient, the patient was included in the study. The medicine was prescribed in different potencies, viz. 30C, 200C and 1M in ascending order, as per the need of the case, in accordance with homoeopathic principles. The progress was noted in a follow up sheet to determine the effects of the medicine.

Result: It was observed that many of the symptoms of Staphylococcinum obtained during the proving of this drug, (conducted by the Council) were present in the patients, which were relieved after administration of Staphylococcinum in this study. Thus the study verifies the symptoms of



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Staphylococcinum obtained earlier during proving of this medicine. The study, in addition, reveals few additional clinical symptoms not obtained in the proving.

Conclusion: Staphylococcinum can be considered as an important medicine for acidity, acne, aphthae, arthritis, dermatitis, fever, headache, toothache and urinary tract infection. In the study, 24 symptoms of Staphylococcinum were clinically verified and 13 clinical symptoms were evolved. All the verified symptoms confirm the scope of its therapeutic action.

Keywords: Clinical verification; Homoeopathy; Nosode; Staphylococcinum.

INTRODUCTION

The term Nosode is used to denote a homoeopathic preparation obtained from microbe or virus cultures, and pathological secretions. The Greek word 'Noso' is a prefix which is added to give the idea of a disease indicating its morbid root. This term is also connected with the Latin word "Noxa", which means noxious or damaged.¹

This definition may apply better to allopathy than to homoeopathy because, in allopathic practice, a vaccine is administered specifically for its own disease, whereas, in homoeopathy, a nosode is given in potentised form on symptom similarity as well as on specific clinical indications. It is in the use of nosodes that the two schools have the most nearly common ground.²

Nosodes are very powerful deep acting remedies made from either diseased product of animal like *Diphtherinum* or of plants like *Secale cor*.³ First generation of homoeopaths who introduced the use of the nosodes were Hahnemann, Hering, Lux, Gross, and Stapf. Hering gathered a tremendous amount of first hand experience in proving nosodes and applying these as remedies in acute and chronic diseases. Hahnemann wanted the nosodes to be well proven before these were entered in the *Materia Medica*. He was quite concerned that homoeopathy might not become mixed with isopathy which gives remedies solely on the basis of causation.⁴

Hahnemann made a short proving of *Psorinum* (the secretion from the scabies vesicle). He placed these nosopathic remedies in his list of antipsoric remedies because their effect upon healthy organisms had not, in his day, been sufficiently ascertained. He also held that *Psorinum* was altered to a homoeopathic remedy by the process of trituration and succussion and that it is a simillimum of the itch virus disease.²

Since Hahnemann's time, through provings and clinical experience, several other nosodes have been added to homoeopathic *materia medica*. They were brought together by H. C. Allen in *Materia Medica* of

the Nosodes. Allen lists the symptoms of *Anthracinum*, *Diphtherinum*, *Lyssin*, *Malandrinum*, *Malaria officinalis*, *Medorrhinum*, *Psorinum*, *Pyrogen*, *Secale*, *Syphilinum*, *Tuberculinum* and *Variolinum*.²

The earliest experiments with nosodes were carried out by Constantine Hering while he was in Surinam, Guiana, South America between 1827 and 1833. Hering spent 5 years studying plant and animal species, he paid special attention to the virulent snake and spider poisons as well as miasmatic substances. He continued to experiment with nosodes of acute and chronic miasms and invited others to conduct provings. He recommended the use of potentized watery excrements of cholera, the black vomit of yellow fever, the desquamated skin of malignant scarlet fever, to bind bags of milk sugar in contact with the skin of typhus patients, the use of leucorrhoeal matter, etc., as well as psorine (*Psorinum*), gleet-matter (*Medorrhinum*), pthisine (*Tuberculinum*) and syphiline (*Syphilinum*).²

Preparation of Nosode

The biotherapeutic Staphylococcinum is prepared from a culture without addition of antiseptic from a mixture of many stocks of *Staphylococcus*. The lysated suspension corresponds to 10 milliards in a cm³ of *Pyogenes aureus Staphylococcus*.¹ In India nosodes are processed from original stock built from isolated microbes, diseased tissues and clinical materials from which the primary stocks are prepared. Depending upon the nature of material used, these are divided into 4 groups, from groups N I to N IV. Group N I contains the preparations made from lysate of micro organisms capable of producing bacterial endo-toxins e.g. *Typhoidinum*, *Paratyphoidinum*, *E. Coli-bacillinum* and *Staphylococcinum* etc.⁵

OBJECTIVES

Primary objective: To clinically verify the symptomatology of Staphylococcinum as observed during the proving of this drug conducted by CCRH.

Secondary objective: To ascertain the clinical symptoms that were not observed during the proving of the drug but observed disappearing in the patients after the administration of the medicine, either completely or partially.

METHODOLOGY

Patients for the study were enrolled from the OPDs of eleven Institutes/ Units of the Council, viz. Central Research Institute, Noida (U.P.), Homoeopathic Drug Research Institute, Lucknow (U.P.), Regional Research Institute, Puri (Odisha), Regional Research Institute, Shimla (H.P.), Regional Research Institute, Gudivada (A.P.), Regional Research Institute, Imphal (Manipur), Dr. Anjali Chatterji Regional Research Institute, Kolkata (W.B.), Clinical Research Unit, Port Blair (Andaman and Nicobar Islands), Clinical Verification Unit, Ghaziabad (U.P.), Clinical Verification Unit, Patna (Bihar), Clinical Verification Unit, Vrindaban (U.P.)

In this multicenter study, 411 patients comprising of 214 males and 197 females were administered prescribed Staphylococcinum according to the similarity of symptoms during the period October 2005- March 2010. The medicine was procured from the licensed pharmacy in various potencies, viz. 30C, 200C and 1M. The selected patients were from all age groups and both sexes. Patients who were on any medication for one week prior to being enrolled in the study were put on a wash-out period of 7 days. The patients, who were suffering from any systemic disease and were under regular medication for that, were excluded from the study. An informed written consent was obtained from the eligible subjects before initiating the study.

The presenting symptoms and signs of the patients were recorded in a predefined case recording proforma. After doing the anamnesis of each enrolled case, special attention was given to the peculiarity of complaints, their characteristic sensations, modalities and any associated or concomitant symptoms with the main complaint (s). Special attention was given to the causation, mental symptoms, thermal reactions,

cravings, aversions, perspiration, sleep, dreams, appetite, thirst, stool, urine etc.

Having noted all these informations, the symptoms were repertorised using a repertory prepared for this purpose by the Council to help the investigator and subsequently consult the Materia Medica, to see the characteristics of the patients with those of Staphylococcinum.

Thus, if Staphylococcinum was found indicated for the patient on the basis of symptom-similarity, it was prescribed in 30C potency twice a day. If Staphylococcinum was not indicated, the patient was excluded from the study and treated in the General O.P.D. of the respective research Institutes/Units. The changes in presenting symptoms and signs were recorded during the follow-up visits. Any kind of improvement was followed by placebo. If there was no change in symptoms and signs even up to seven days, the next higher potencies like 200C and 1M potencies were prescribed. If no change was observed, even after change of potencies, the case was closed and considered as a clinical failure. If the patient presented with new symptoms of mild intensity, placebo was prescribed; while appearance of severe symptoms, sufficient to cause considerable discomfort to the patient, called for change of medicine or therapy.

RESULTS

The data of all the cases were collected, compiled and thereafter analyzed. The clinically verified symptoms are given in Table-1 along with the number of patients prescribed on the basis of symptoms available or proving records (drug proving profile generated by CCRH) and also the number of patients who got relief after administration of Staphylococcinum. The numerical superscripted along with the symptoms in the Table1 denote the literatures cited. Elements of the main symptom (character, modalities, concomitants, etc.) which was not observed during the proving but

Table 1: Clinically verified symptoms observed during the study

Location	Symptom(s)	Improvement Status
MIND	Irritability < evening, noise > lying down in dark ⁶	12,7
	during pain in boils	2,2
HEAD	Headache < morning ⁶ with vertigo	8,7
	Throbbing pain in forehead > by rest, pressure, after sleep < after lunch ⁶ , morning	6,4
	Bursting pain in head > by pressure ⁶	32, 26
	Severe throbbing pain in forehead agg. sunlight amel. from rest & pressure ⁶	42,33

Location	Symptom(s)	Improvement Status
FACE	Acne enormous, painful, on face, pain > after sleep ⁶ < sun light Acne ⁶ with itching with suppuration oozing thick pus < cold season	17, 11 1,1 1,1
MOUTH	Aphthae with ulcers inside lower lip and pricking pain > warm drink ⁶ Tasteless ⁶	30,26 37,30
TEETH	Toothache < cold water, night, > by hot drink ⁶	11,10
STOMACH & ABDOMEN	Appetite diminished ⁶ Nausea with diminished appetite ⁶	43,33 14,10
RECTUM & STOOL	Stool unsatisfactory, irregular with pain in abdomen ⁶ Stool soft with tenesmus, unsatisfactory > by passing stool ⁶	29,20 4,2
URINARY SYSTEM	Burning micturation ⁶	17,11
FEMALE	Itching in vulva without eruption, < morning, night. > scratching ⁶ , after bathing.	3,3
EXTREMITIES	Pain in left shoulder joints > by pressure ⁶ Pain in knee < standing, sitting & walking ⁶ Pain in left elbow < rising in morning ⁶	6,3 14,11 4,2
FEVER	Fever with chill & body ache > evening, followed by heat & perspiration ⁶	23,17
SKIN	Papular, vesicular eruption on thigh, hips & buttock with itching, sticky discharge > applying cold water ⁶ Papular eruption on back of finger watery thin discharge, itching followed by burning sensation ⁶ Boil on right ⁶ knee, in the axilla & back > by cold Itching ⁶ < night	6,4 9,7 1,1 1,1

Table 2: Clinical symptoms

Location	Symptom(s)	Improvement Status
NOSE	Coryza with thin nasal discharge with sneezing < morning	1, 1
MOUTH	Pricking pain in tongue & cheek < eating	1,1
TEETH	Pain in upper molar teeth	1,1
THROAT	Pain in throat	1,1
STOMACH & ABDOMEN	Thirst with dryness of mouth Sour eructation < empty stomach	1,1 1,1
GENITALIA -FEMALE	Leucorrhoea scanty, thin, watery, whitish	1,1
RESPIRATORY SYSTEM	Recurrent attack of cough & cold Cough with easy expectoration especially in day time Cough dry < at night while lying down	1,1 2,2 1,1
EXTREMITIES	Aching pain in lumbosacral region < sitting while, > lying down	1,1
SKIN	Recurrent boils on whole body	1,1
SLEEP	Sleep disturbed due to anxiety	1,1

disappeared in the patients during the study either completely or partially and are not mentioned in the referred literature has been kept along with the main symptom in italics. In the column 'Improvement status', the first figure denotes the number of patients who had the symptom and to whom the medicine was prescribed and the second figure denotes the number of patients who got relief of the same symptom.

Table 2 contains those symptoms which are not found in the proving literature of the medicine, but found to have disappeared after the administration of Staphylococcinum, otherwise known as clinical symptoms.

REPERTORY

A concise repertory of the verified symptoms according to the structure of the Kent's Repertory of the Homoeopathic Materia Medica has been compiled for quick reference. Rubrics and sub-rubrics in italics are new rubrics i.e. not mentioned in Kent's repertory while rubrics and sub rubrics in roman letters are existing rubrics of the said repertory which were reconfirmed through verification in this study.

MIND

IRRITABILITY

evening
lying down in dark, amel.
noise, from
pain, during (*boils from*)

HEAD

PAIN

morning
pressure amel.
vertigo, with
bursting

PULSATING, throbbing

Forehead

morning
lunch after,
pressure amel.
rest, amel.
sleep amel.
sunlight, from

NOSE

CORYZA

morning
discharge, (fluent), *thin*
sneezing with

DISCHARGE, thin

morning

FACE

ERUPTIONS, acne, enormous

cold season, in
itching, with
pain, with
sleep, amel.
sunlight, from
suppurating & oozing of thick pus, with

PAIN

pricking
Lips inside, lower
warm drinks, amel.
cheek bones, eating after

MOUTH

APHTHAE, inside lower lip

PAIN

pricking
Tongue, eating after

ULCERS

Lips, inside of, lower
pricking pain, with
warm drink, amel.

TASTE

wanting, loss of taste

TEETH

PAIN, toothache in general

night
cold, water, from
warm drinks, amel.
molars, upper teeth

THROAT

PAIN

STOMACH

APPETITE

diminished
nausea, with

ERUCTATIONS, sour

empty stomach, from

THIRST

dryness of mouth, with

RECTUM

PAIN, tenesmus

stool, after, amel.

URGING, desire

irregular

STOOL

IRREGULAR

INSUFFICIENT

SOFT

tenesmus, with

URETHRA

PAIN, burning
urination, during

GENITALIA-FEMALE

ITCHING
morning
night
bathing, after, amel.
cold food, amel.
eruptions, without
scratching amel.

LEUCORRHOEA

scanty
thin, watery
white

COUGH

DRY
night
lying agg.

EXPECTORATION

EASY
daytime

CHEST

ERUPTIONS
Axilla, boils
cold, amel.

BACK

ERUPTIONS, boils
cold, amel.
PAIN, aching
Lumbo-sacral region
lying down, amel.
sitting, while

EXTREMITIES

ERUPTION
Fingers, *back of*
discharge, thin watery, with
followed by burning
itching
Hip
itching, with
vesicular
itching, with
cold water amel.
sticky discharge, with
Knee
boils, on right side
cold water amel.
Nates
papular
cold water, amel.

itching, with
vesicles
sticky discharge, with
cold water, amel.

Thigh

papular
itching, with
vesicles
cold water amel.
sticky discharge, with
itching

PAIN

Shoulder, left
pressure amel.

Elbow, left
morning
rising, after

Knee

sitting, while
standing, while
walking, while

SLEEP

DISTURBED, *family problem, from*

FEVER

EVENING, *amel.*
bodyache, with
CHILL, with
heat and perspiration

SKIN

ERUPTIONS
boils, recurrent
papular
ITCHING, *night*

GENERALITIES

COLD, *tendency to take*

DISCUSSION

The study revealed that Staphylococcinum is having specific affinity for gastrointestinal system, head, fever, urinary system, skin and locomotor system.

Its action on gastrointestinal system has been verified like symptom of diminished appetite with nausea. It has action on the intestines producing dysentery, where there is marked tenesmus, unsatisfactory, irregular stools and pain in the abdomen. There is tenesmus in rectum even while passing soft stool.

There are aphthous ulcers inside mouth (lower lip) with typical pricking pain in aphthae, ameliorated from warm drinks. There is also toothache, which is aggravated at night and from cold drinks and relieved from warm drinks.

It produces severe throbbing and bursting type of pain, which is marked in morning, aggravated by exposure to heat of sun and ameliorated by pressure and taking rest.

Its role in alleviating fever, in all the three stages, has been verified during the study.

In urethra, it is found to relieve burning pain during micturition.

Its affinity for joints, specifically shoulder, knee and elbow joints has also been confirmed during the study. The joint pains are aggravated by standing, sitting, walking and ameliorated from pressure.

On the skin, it produces acne, papular, vesicular eruptions and boils. The eruptions are marked with itching and it is followed by burning. The vesicular eruptions are characterized with thin watery discharge, associated with itching and burning. The medicine was also found useful in boils and there was a relief from cold water in such condition.

It is found to be a very useful medicine in pruritus vulvae, which is aggravated in morning and at night and temporarily ameliorated after scratching.

Besides these, the symptoms like recurrent cold; coryza with thin nasal discharge in morning; throat pain; sour eructation in empty stomach with dryness of mouth; dry cough on lying down; lumbago; disturbed sleep following anxiety and leucorrhoea have also been verified during study. These were the clinical symptoms of Staphylococcinum.

CONCLUSION

Results obtained show that Staphylococcinum can be considered as an important medicine for acidity, acne, aphthae, arthritis, dermatitis, fever, headache, toothache and urinary tract infection. During the study twenty four out of thirty seven symptoms during the drug proving conducted by the Council earlier, were verified, along with a good number of additional clinical symptoms, which were relieved wholly or partially during the study in the patients.

Based on these findings it may be said that the drug was amply verified. All these verified symptoms confirm the scope of its therapeutic action. Further studies may be conducted to re-verify the symptoms and to deduce its clinical importance again so that more reliable characteristics of Staphylococcinum can be ascertained.

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