

CLINICAL RESEARCH

An open clinical observational study on the usefulness of pre-defined homoeopathic medicines in the management of chronic sinusitis

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Objective: To ascertain the usefulness of 17 pre-defined homoeopathic medicines in the management of chronic sinusitis.

Methods: This is an interim analysis of the open clinical observational study conducted by the Regional Research Institute (Homoeopathy), at Shimla (Himachal Pradesh) under Central Council for Research in Homoeopathy from October 2005 to March 2009. Ninety seven patients suffering from chronic sinusitis were enrolled in the study; 51 patients completed the treatment and follow up period of 6 months and were assessed using chronic sinusitis symptom score (CSSS). Seventeen pre-defined medicines in centesimal scale of potencies (30C, 200C and 1M) were prescribed.

Results: Outcome assessment of patients reflects 88 % improvement in varying degrees; marked improvement in 31(61%) patients, moderate in 10 (20%) patients and mild improvement in 4 (8%) patients. *Silicea*, *Kali bichromicum* and *Calcarea carbonica* were frequently indicated, were prescribed in 30C & 200C potencies and improved 34 (88.23%), 6 (100%) and 7 (86%) patients respectively.

Conclusion: The data of this interim analysis of the study though shows positive effects of homoeopathic medicines in patients suffering from chronic sinusitis, the outcome of the final multicentre study on this disease will help in reaching at certain conclusion.

Key words: homoeopathy; chronic sinusitis; interim analysis; observational study; silicea; kali bichromicum; calcarea carbonica.

Introduction

Chronic sinusitis causes significant health hazards in our everyday life¹. Newer classifications of sinusitis refer to it as Rhinosinusitis, as the inflammation of the sinuses cannot occur without some inflammation of the nose as well (Rhinitis). Its prevalence is rising and generates significant health care costs².

Respiratory tract infections are the most common type of infections managed by health care providers.³ Of all the respiratory infections, sinusitis is one of the most common illnesses that affect a high proportion of the population. According to the

National Ambulatory Medical Care Survey data, sinusitis is the fifth most common diagnosis for which an antibiotic is prescribed⁴.

The causes of chronic sinusitis are poorly understood and may include allergy, environmental factors such as dust or pollution, bacterial infection, or fungus (allergic, infective, or reactive)⁵. Antibiotics in bacterial sinusitis do not always bring medium to long-term relief, and are often followed by persistence of symptoms leading to a chronic state of sinusitis that is very difficult to treat successfully. On the other hand, clinicians should weigh the moderate benefits of antibiotic treatment against the potential for adverse effects.⁶

Homoeopathic medicines are cost effective⁷. These are also safe and promising in treating chronic sinusitis⁸. Attempts have also been made

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by some researchers with homeopathic combinations and have shown to produce positive results^{9,10,11,12,13,14,15}. This article reflects the interim analysis of the study on chronic sinusitis with 17 pre-defined homeopathic medicines, at Regional Research Institute (Homoeopathy), Shimla (Himachal Pradesh) under Central Council for Research in Homeopathy.

Material and Methods

Study design

The study was conducted from October 2005 to March 2009 with the objective to assess the usefulness of a group of 17 pre-defined homeopathic medicines in treating chronic sinusitis. This article shows the analysis of the data of 51 patients who completed the study out of 97 patients enrolled at Regional Research Institute (Homoeopathy), Shimla (Himachal Pradesh). Clearance of the Ethical Committee and informed consents from the patients were obtained before initiation of the study. Patient's symptoms and signs were quantified on 17 symptoms and signs of chronic sinusitis known as chronic sinusitis symptom score (CSSS) which was developed by the Council (Table 1).

Study sample

Patients enrolled were of both sexes, ranging from 10 to 60 years, presenting with illness of more than 12 weeks, consisting of symptoms like nasal obstruction, nasal discharge, epistaxis, facial pain or pressure, anosmia or hyposmia and headache supported by x-ray findings of sinusitis were included in the study. The patients who were on any other therapy were given a washout period of 15 days before giving the prescription.

Patients suffering from sinusitis of less than 12 weeks duration, with diabetes mellitus and other systemic diseases, nasal polypus, severe deviated nasal septum, chronic sinusitis with complications (orbital cellulitis, orbital abscess, frontal subperiosteal abscess, epidermal abscess, subdural empyema, meningitis, cerebral abscess, dural vein thrombophlebitis, cavernous sinus thrombosis) were excluded.

Selection of trial medicines

Seventeen pre-defined trial medicines were selected by repertorising the diagnostic symptoms of chronic sinusitis¹⁶. The repertorisation was done using the complete repertory in *Cara* professional¹⁷.

Seventeen medicines which belonged to either 2nd or 3rd grade for the rubric "Inflammation, chronic sinusitis" were considered. These are: *Kali bichromicum*, *Kali iodatum*., *Calcarea carbonica*, *Phosphorus*, *Mercurius solubilis*, *Arsenicum album*, *Hepar sulphuris calcareum*, *Pulsatilla nigricans*, *Sanguinaria canadensis*, *Silicea*, *Thuja occidentalis*, *Lycopodium clavatum*, *Hydrastis*, *Kali chloricum*., *Cuprum metallicum*, *Nux vomica*, *Kreosotum*. On the basis of the totality of symptoms of each patient, the simillimum was selected out of these 17 pre-defined homeopathic medicines and prescribed in centesimal potency (30C). *Materia Medica* was referred after thorough case taking for determining the simillimum.

Treatment and follow up schedule

The first prescription from amongst 17 medicines was made on the basis of repertorisation of the presenting signs and symptoms of the disease guided by the characteristic particulars, mental/emotional and physical attributes of the patient. Medicines were prescribed in centesimal scale of potency starting with single dose of 30C potency, 4 globules of size 30 followed by placebo (globules), next day onwards, three times a day for two weeks. Follow-up was provided weekly for 1st month, fortnightly for the next 2 months and monthly visit onwards upto 6th month. Repetitions of indicated medicines were done depending on the intensity of the symptoms; 200C and 1M potencies were prescribed subsequently after the 30C acted but did not relieve completely. All follow up actions were taken as per the guidelines of Kent¹⁸. Change of prescription was allowed twice only for each patient. Steam inhalation, avoidance of allergens and cold exposure were advised to the patients as a part of non-medical management.

Outcome assessment

Primary outcome measure was reduction in CSSS score. Improvement was calculated using formula $\{[(\text{baseline score} - \text{score at end}) / \text{baseline score}] \times 100\}$. Changes thereupon were graded as: cured (100% improvement), *marked improvement* (75 to < 100% improvement), *moderate improvement* (50 to < 75% improvement), *mild improvement* (25 to < 50% improvement), *not significant improvement* (< 25% improvement), *static* (no change), and *worse* (increase in symptom score).

Results

Fifty one patients, who completed their follow up of 6 months at Regional Research Institute

Table 1: Chronic sinusitis symptom score (CSSS)

Symptoms/signs of chronic sinusitis	Score			
	0	1	2	3
Nasal Obstruction	Nil	Some time of the day	Always	Bilateral compelled to breathe through mouth
Posterior nasal dripping	Nil	Infrequent	Frequent	
Nasal discharge	Nil	Mucoid	Mucopurulent	
Headache	Nil	Mild - moderate	Severe	
Facial pain or pressure	Absent	Present		
Sense of smell	Normal	Hyposmia	Anosmia	
Epistaxis	Absent	Present		
Cough	Nil	Infrequent	Frequent	
Halitosis	Absent	Present		
Fever	Absent	Present		
Nasal mucosa	Normal	Swollen and red		
Turbinates	Normal	Swollen		
Maxillary tenderness	Absent	Present		
Frontal tenderness	Absent	Present		
Ethmoidal tenderness	Absent	Present		
Pharyngeal examination	Healthy	Unhealthy		
X-ray Sinuses	Normal opacity & mucosal thickening	Haziness / Opaque		

Intensity of disease according to Score - Mild: 3 – 10 Moderate: 11 - 17 Severe: 18 - 24

(Homoeopathy), Shimla were included in this interim data analysis. Sixty percent of the patients (i.e. 31 patients) were in the age group of 21-40 years. Several predisposing factors like hypertrophied turbinates (78%), allergic rhinitis (20%), deviated nasal septum (2%), adenoids (27%), and dental infection (65%) are identified to be responsible for the evolution of chronic sinusitis. The most common form of sinusitis in this study is maxillary (n=32) and fronto-maxillary (n=19) sinusitis.

At the baseline, the patients most commonly experienced with nasal obstruction (96%), headache (100%), facial pain (100%), post nasal dripping (PND) (96%), nasal discharge (96%) and

Table 2: Duration of disease

Groups	No. of patients
6 mnths - < 1 yr	1
1 yr -< 2 yrs	2
2 yrs - < 3 yrs	2
3 yrs - < 4 yrs	7
5 yrs - < 7 yrs	7
7 yrs - < 10 yrs	4
10 yrs - < 15 yrs	7
15 yrs - < 20 yrs	8
>20 yrs	13

cough (86%), sense of smell (perverted) (94%), epistaxis (45%), halitosis (76%), fever (78%). After treatment, reduction of symptoms was noted in nasal obstruction (98%), PND (82%), nasal discharge (88%), headache (80%), facial pain (63%), halitosis (87%), cough (82%), epistaxis (87%), sense of smell (perverted) (83%) and fever (82.5%). These symptoms reduced significantly after homeopathic treatment for 6 months (Table 4). Improvement in radiological findings was observed in 59% of the patients and worsening was observed in 14% at the end of 6 months.

At the completion of the study, outcome assessment shows 61% marked improvement, 20% moderate, and 8% mild improvement. No significant improvement was observed in 10% and no change in symptoms was observed in one patient.

Out of the 17 pre-defined medicines only 6 medicines which were prescribed are: *Calcarea carbonica* (30C, 200C, 1M), *Kali bichromicum* (30C, 200C, 1M), *Lycopodium clavatum* (30C, 200C, 1M), *Hepar sulphuricum* (30C, 200C), *Pulsatilla* (30C, 200C), and *Silicea* (30C, 200C, 1M). *Silicea* and *Calcarea carbonica* were indicated in 67% and 14% of the patients respectively with 86% improvement observed in the former and 88% of improvement in the latter. The details of these are mentioned in Table 4. The prescribing indications are mentioned in Table 5.

Table 3: Symptoms and signs

Symptoms/ Signs	No. of patients	
	At baseline	Improved at the end of treatment
Nasal Obstruction	49	48
Post nasal drip	49	40
Nasal discharge	49	43
Headache	51	41
Facial pain or pressure	51	32
Sense of smell (perverted)	48	40
Epistaxis	23	20
Cough	44	36
Halitosis	39	34
Fever	40	33
Tenderness in frontal sinus	50	35
Tenderness in Maxillary sinus	45	31
Nasal congestion on both sides	48	32
Hypertrophy of nasal turbinates on both sides	40	32
Purulent discharge per nose	46	40
Pharyngeal congestion	50	32

Table 4: Details of pre-defined trial medicines used

Name of the Medicine and potencies	No. of Patients					
	Prescribed	Marked improvement	Moderate improvement	Mild improvement	Improve ment not significant	Worsened
Calcarea carbonica 30C, 200C,1M	07	6	0	0	1	0
Silicea 30C, 200C, 1M	34	20	7	3	3	1
Hepar sulph 30C, 200C	01	1	0	0	0	0
Kali bich. 30C, 200C, 1M	06	3	2	1	0	0
Lycopodium 30C, 200C, 1M	01	0	1	0	0	0
Pulsatilla 30C	02	1	0	0	1	0

Table 5: Prescribing indications of the trial medicines used in the study

Name of medicine	Prescribing Indications ¹⁹
Calc. carb.	<ul style="list-style-type: none"> – Forgetfulness, confused, fear of darkness, obstinate (4) – Aversion to work (2) – Fair, fatty and flabby; chilly patient with tendency to catch cold (6) – Pale and chalky look (2) – Craving for indigestible things such as dry raw rice, slate, pencils (2), sour food (3) – Aversion to milk and sweet (1) – Intolerance to milk (1) – Perspiration on scalp during sleep which wets the pillow (1) – Easily gets tired on slightest climbing (2) – Tendency to get cramps and sprains (2) – Nasal complaints < change of weather (1) – Pain in eyes from artificial light, sun light and glare of heater/fire (2) – Watering and itching in eyes from sun heat (2) – Skin trouble > by cold and < by hot (1) – Headache > by closing eyes (1) – Pain in breast > by flow of menses (1) – Premature caries of teeth (1) – Complaints < by working in cold water (1), < after bathing (1)
Silicea	<ul style="list-style-type: none"> – Obstinate, nervous, yielding disposition, biting of nails during mental tension, anxious (6) – Dreams of daily activities (1) – Extremely chilly patient with tendency to catch cold (30) – Sensitive to noise and strong odour (14) – Desire for ice cream but intolerance to it (4) – Aversion to milk (1) – Offensive sweat of feet and axillae (19) – Tendency to suppuration (2) – Coldness of hands and feet < winter (8) – Icy coldness of feet < winter (9) – Pain in hand from washing with cold water (1) – Nasal complaints < in morning (13), offensive nasal discharge (1), chronic coryza and sneezing (6) – Caries of root of teeth (6) – Headache < excess of sun heat and overheating (2), > sleep during (5), > wrapping head with warm garments (8), > by closing eyes (4) – Teeth sensitive to both hot and cold things (2) – Pain in eyes < light (3), colourful circles before eyes (1) – Complaints < in open air (1), < uncovering (2), change of weather (9), and < in winter season and < from cold – Complaints > by wrapping body with warm garments (15), > from warmth (30), > in summer season (17) – Premature graying of hair (1)
Hep.sulph.	<ul style="list-style-type: none"> – Irritable, easily excited (1), hasty talking (1), sensitive to all impressions (1) – Extremely chilly patient with tendency to catch cold (1) – Highly sensitive to the slightest draft of cold air (1) – Desire for sour things and salty things (1) – Excessive offensive sweating on palms, soles and in axillae (1) – Complaints < cold or uncovering (1), < from cold food and sour food (1), – Complaints > by warmth (1)

Name of medicine	Prescribing Indications ¹⁹
Kali bich.	<ul style="list-style-type: none"> – Constant hawking to take out discharge in the morning (3), Sun headache (1) – Dry scabs/ crusts from nose in the morning (5) – Discharges from nose are thick, yellowish, greenish, stringy, sticky (6), difficult to come out (2), viscid, tough from posterior nares (4) – Coryza with obstruction of nose (1) – Foetid smell in nose (3), loss of smell (3) – Pain, soreness and bleeding from nose on removing dry scabs (2), dry scabs re-forms in nose after removing it with dryness in nose (3) – Pain and heaviness over eyebrow and in glabella region (1) – Complaints < in morning (6), > after warm water bathing (1)
Lycopodium	<ul style="list-style-type: none"> – Hot patient (1) – Desire for warm drinks (1) – Excessive sweating in warm weather (1) – Cramps in calves at night (1) – Nose and throat complaints > from warm drinks (1); dryness in nose with crusts (1) – Cough > by walking/ motion (1) – Falling of hairs from vertex with baldness and dandruff (1) – Constipation, stool hard and difficult to defecate (1)
Pulsatilla	<ul style="list-style-type: none"> – Emotional, sensitive (1) – Weeping disposition (1), consolation > (1) – Dryness of mouth and throat with thirstlessness (1) – Complaints < in morning (1), < dampness (1), in cloudy weather (1); > in open air even though feels coldness in body (1) – Nasal and post-nasal discharge mostly greenish, sometimes yellowish (1)

Discussion

A group of 17 pre-defined trial homeopathic medicines were used in the management of patients suffering from chronic sinusitis. Fifty one patients were followed up and completed the treatment and follow up for six months. In this study maximum numbers of patients suffering from chronic sinusitis were males than their female counterparts which are contrary to the findings of National Health Interview Survey 2001²⁰.

Hypertrophied turbinates (40 patients) is the major factor for the increased prevalence of chronic sinusitis. Other factors responsible are: dental infection (33 patients), deviated nasal septum (1 patient), and allergic rhinitis (10 patients); this corroborates with the reviews of Spector²¹ and Kim²².

A controlled randomized double-blind trial carried out by the physicians in private practice with homeopathic combinations in sinusitis, showed the recovery in 81% of the patients with acute sinusitis & 67% of the patients with chronic sinusitis²³. In our study, the individualized homeopathic medicines in single doses, were able to recover the patients suffering from chronic sinusitis symptomatically and radiologically in 88.2% patients and 43.1% patients respectively.

The maxillary sinusitis is the commonest form of sinusitis and may occur alone or with involvement of

the other sinuses. The discharge is frequently foul, and where the origin of disease lies in a dental infection²⁴. In our study, it is observed that 64.7 % of patients suffering from chronic maxillary sinusitis suffered from dental infection and apart from this we observed that these patients extremely foetid nasal discharge.

Maximum number of patients (n= 42) suffering from chronic sinusitis were found to be chilly and their complaints were worse from exposure to cold weather/ change of weather and taking cold things, better by warmth in general. It may be due to continuous exposure to cold weather or continuously living in cold environment typical to the climate at Shimla. Due to this climatic condition, such exciting cause of chronic sinusitis may turn as maintaining cause, which may act as hindrance in complete recovery in many cases and cause relapses. Concurrently, the medicines found useful were chilly remedies as categorized by Gibson and Miller²⁵, i.e. Calc.carb. (n= 07 patients), Silicea (n=34 patients) and Hepar. sulph. (n= 01 patient). After treatment with these remedies, frequent relapses could be reduced. But due to lack of control group the bias cannot be avoided.

In this analysis it was found that the most frequently indicated medicines were *Silicea* and *Calcarea carbonica* which is in consonance with the findings of Sharma et al²⁶ and Ismail⁸. The symptoms on the basis

of which the indicated medicines were prescribed were also recorded²⁷ as mentioned in *Materia Medica* but the verification of these could not be done which needs a separate study with large sample size for each symptom of the medicine prescribed.

Conclusion

The results of the interim analysis of this study though positive, are preliminary and the analysis of the final multicentre data will help in reaching at definitive conclusion.

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