Original Article

A randomised, double-blind, placebo-controlled and parallel-arm trial to assess the effect of homoeopathic medicines on chronic rhinosinusitis

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Abstract

Background: Chronic rhinosinusitis (CRS) is a significant health problem impacting health related quality of life. **Objectives:** This study assesses the efficacy of individualised homoeopathy (IH) in LM potency in CRS. **Methods:** A randomised, double-blind and placebo-controlled trial on patients with CRS was undertaken at four institutes, from July 2012 to December 2013. Eligible participants were randomised to IH in LM-potencies (n = 60) or a similar placebo (n = 60). Primary outcome was change in the total symptoms score (TSS) (area under the curve [AUC]) and in sinus nasal outcome test 22 over 3 months. Intention-to-treat approach was used for analyses. **Results**: TSS AUC over 3 months was less in the homoeopathy group compared to the placebo group but was statistically insignificant (IH: 1303.1 ± 612.2; P = 1380.1 ± 811.8; 95% CI: −336.9, 182.9; P = 0.56). The absolute difference in TSS from baseline had a statistically significant difference at day 60 (mean difference = 4; 95% CI: 0.3–7.7, P = 0.03) and day 75 (mean difference =3.8; 95%: 0.1–7.5, P = 0.04) favouring homoeopathy. The global assessment by the investigator and patient showed satisfactory improvement at day 60 mean difference = 0.6, 95% CI: 0.27–0.86, P = 0.0001 and day 75 mean difference = 0.5, 95% CI: 0.27–0.84, P = 0.0001, respectively. A positive trend was observed in rhinoscopy score in homoeopathy group (mean difference: 0.9, 95% CI: −0.00–1.8, p=0.05). There was no difference in computed tomography scan scores of paranasal sinuses between the groups. **Conclusion:** This study provides a positive trend to support the effect of individually selected homoeopathic remedies in patients with CRS and warrants further evaluation.

Keywords: Chronic rhinosinusitis, Individualised Homoeopathy, Randomised controlled trial, Sino-nasal outcome test-22, Total symptoms score

Introduction

Chronic rhinosinusitis (CRS) is the most common upper respiratory tract infections. It is the chronic or acute, unilateral, or bilateral inflammation of the mucous membrane of the nose and one or more paranasal sinuses. When the symptoms and signs persist for 12 or more weeks with no complete resolution, it is said to be chronic.[1] The cause of CRS is multifactorial; anatomic, genetic and environmental, leading to a vicious cycle of infection, swelling and blockage.[2] It is characterised by two or more symptoms like anterior or posterior nasal discharge, nasal blockage or congestion, reduction or loss of smell, facial pain or pressure plus either endoscopic signs of polyps or discharge or edematous mucosa in middle meatus suffered for 12 weeks or more.[2] An estimated 134 million Indians, that is, one in eight Indians suffer from chronic sinusitis in India, having great personal and economic impact.[3]

It is the leading cause of poor health interfering with patients' quality of life and in turn loss of productive time.[4] A wide range of medical/surgical modalities is available for its management. Medical therapy includes antibiotics, corticosteroids, decongestants, antihistamines, mast-cell stabilisers, anti-leukotrienes, nasal douching, immunotherapy

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and reduction of environmental factors are used frequently.[2] It is considered to be the fifth most common disease for an antibiotic prescription.[5] Overuse and inappropriate selection of antibiotic drugs are associated with increased drug resistance for respiratory pathogens leading to chronic disease and increased treatment costs.[5,6] Further, the use of systemic steroids for long- and/or short-term CRS is debatable and benefits over risks are case to a case basis.[7]

Nasal saline irrigation (both as a sole modality and as an adjunct to medical treatment) is found to be beneficial,[8] while surgical treatment is reserved for refractory cases only.[9] Although ample treatment alternatives exist, the complete treatment of CRS remains an unmet need and no treatment regimen is found to be complete treatment.[10]

Homoeopathy has been playing a key role in managing respiratory disorders.[11] It has been observed that patients seeking homoeopathic treatment had a better overall outcome than those on conventional treatment. Available evidence shows the effects for both individualised and complex homoeopathic treatment for sinusitis. Much research has been done with complex homoeopathy showing clinical effectiveness for sinofrontal with reduced cost.[12,13] Studies with individualised homoeopathic treatment on sinusitis have also shown improvement in symptoms as well as the quality of life.[14,15] Witt *et al.*[14] studied 134 patients of chronic sinusitis on homoeopathic treatment and found significant improvement. Nayak *et al.*[13] reported a cohort study on 550 patients with improvement in symptoms of sinusitis by 3 months, along with radiological improvement over a period of 6 months of follow-up.

The above studies with individualised homoeopathic treatment add to hypothesis-generating studies. Therefore, a randomised, double-blind and placebo-controlled trial was undertaken to evaluate the efficacy of individualised homoeopathic medicines in managing CRS.

Materials and Methods

Study design and setting

A randomised, double-blind and placebo-controlled parallel arm trial was conducted between July 2012 to December 2013 at four centers Central Research Institute (H), Noida (Now Dr. D. P. Rastogi Central Research Institute, Noida), Regional Research Institute (H), Guwahati, Regional Research Institute (H), Jaipur (Now Central Research Institute) and Regional Research Institute (H), Shimla. All procedures were in accordance with the guidelines of Good Clinical Practice, India.[16] and Helsinki Declaration of 1975, as revised in (2013).[17] The trial is registered at Clinical Trial Registry, India on 3 January, 2012 (CTRI/2012/01/002320). The protocol was approved by the Institutional Ethics committee of the council and is published.[18]

Patients were enrolled in the study after fulfilling the study criteria and obtaining written informed consent. The investigators responsible for prescription were institutionally qualified homoeopathic physicians with an experience over 20 years. They were trained and sensitised about outcome tools used for assessment and other protocol aspects. The pharmacists were trained in the blinding, and concealment procedure. Modern medicine ear, nose and throat (ENT) consultants were engaged at each center for proper diagnosis and assessment during follow-ups.

Participants

Patients suffering from CRS were enrolled as per the preset inclusion and exclusion criteria.

Patients suffering from CRS (with or without nasal polyps) as defined in European Position paper on rhinosinusitis and polyps 2007,[2] aged 18–60 years, of both genders, with presence of two or more symptoms one of which was nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip), with or without facial, pain/pressure, with or without reduction or loss of smell for >12 weeks and written informed consent were included in the study.

Patients with a serious underlying medical condition (e.g., severe renal or hepatic disease), history of malignancy, patients who had taken any medication before entry into the study (were enrolled after washout period of 15 days), patients who had taken topical steroids within 4 weeks before the study therapy (were enrolled after washout period of 1 month), atrophic rhinitis, complications of CRS, significant psychological problems and pregnant lactating women were excluded form the study.

Intervention sample size

The allocation of intervention, a priori was designed to allocate in the ratio of 2:1 (Homoeopathy: Placebo). The effect size in the previous study was found to be 0.8. Therefore, in this present study, using an effect size of 0.8, with power 95%, $\alpha = 0.05$, intervention: placebo = 2:1, the sample size was calculated to be 63:31. Therefore, 94 subjects were required. As the trial was multi-centric (four centres), for equal distribution, considering 10% drop out rate, the total sample size was rounded to 120 patients. However, for statistical rigor, the allocation was made in the ratio of 1:1.

Randomisation and allocation

The investigators and participants were blinded to the intervention allocation. The pharmacist dispensed medicines according to a randomised assignment sequence to homoeopathy or placebo group, generated by http://www.randomizer.org/ in the ratio of 1:1. Only the principal investigator and the coordinating team had access to the randomisation codes, and none of these were involved in the patient's assessment.

Individualised Homoeopathic intervention (IH)

After enrollment, the patient's symptoms were analysed, repertorised and a group of medicines was short-listed. The final selection of medicine was made in consultation with materia medica. Patients were then randomised to either the

homoeopathic group or the placebo group. Before prescription patients were kept for a run-in period of 14 days to ensure the presence of symptoms suffered and to remove the effect of treatment taken if any.

IH in LM-potencies (0/1–0/14) was started with 0/1 potency (in both acute and chronic cases) followed by successive higher potencies for 3 months.[19] The medicine was prepared with one globule (poppy-seed size) of the medicine dissolved in 120 mL of distilled water; containing 2.4 ml (2% v/v) dispensing alcohol followed by ten uniformly forceful downward strokes against the bottom of the phial. Patients were instructed to mix 3 teaspoonful (15 mL) of the solution with 8 teaspoonful (40 mL) of water in a glass stirred thoroughly and to take one teaspoonful (5 mL) of this medicinal solution as one dose, rest to discard. The next dose of the same potency or the next potency was prepared fresh every time by the same procedure.

At each follow-up, change in symptoms after administration of medicine or placebo was monitored based on homoeopathic principles. In chronic cases, the medicine was repeated every day or every alternate day in a single dose while in acute episodes, 2–6 hourly or even oftener depending on the intensity of symptoms.

Placebo

Patients in the placebo (Pl.) group received placebo in a similar manner as of the homoeopathic group. However, it constituted of an un-medicated poppy-size sugar globule impregnated with dispensing alcohol, and any change triggered after administration was followed by placebo only.

Other remedy

If the patient had a worsening episode or increased discomfort of the existing symptoms, saline nasal spray was advised to both groups as a temporary relief remedy. The use of saline spray was based on the judicious decision by the investigator/ENT consultant.

Outcomes

The primary outcome measures were area under the curve (AUC) in the total symptoms score (TSS)[2] over 3 months from baseline and changes in sinus nasal outcome test 22 (SNOT-22)[20] in 3 months. SNOT-22 is a revised version of SNOT-20[21] with two additional items addressing nasal obstruction and smell/taste problems. Both the TSS and SNOT-22 were assessed every 15 days for a period of 3 months. The secondary outcome measures were as follows: change in SNOT-22 at 6th month, change in nasal rhinoscopy[22] (at 3 and 6 months) and change in sinuses through computed tomography (CT) scan (over 3 months) using Lund-Mackay[23] score (LMS) which gives a maximum score of 24 or 12/side covering all the sinuses, change in absolute eosinophil count (AEC) (over 3 months), number of acute exacerbation-chronic rhinosinusitis (AE-CRS) during the observation period supported by rhinoscopy findings, number of AE-CRS in between the groups and changes in global assessment by the patient (PtGBA) and physician (PhGBA) (at 3 and 6 months).

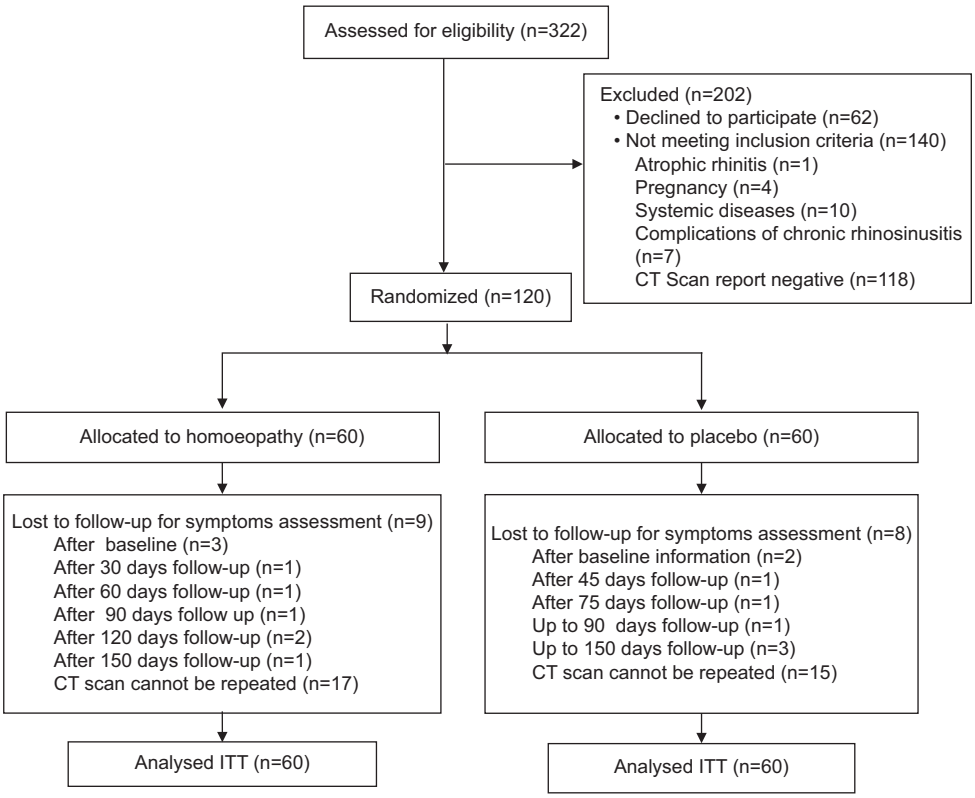

Figure 1: Flow chart

Table 1: Baseline demographic and clinical characteristics

Variables	Homoeopathy (*n*=60) *n* (%)	Placebo (*n*=60) *n* (%)	*P* value
Gender			
Male	27 (45.0)	37 (61.7)	0.07
Female	33 (55.0)	23 (38.3)	
Age	34.1±9.7	35.5±9.7	0.43
Illness (years)	8.9±6.9	6.7±6.2	0.08
TSS	27.8±9.2	26.4±10.7	0.42
SNOT-22	53.9±21.4	53.8±21.9	0.99
CT-scan (Lund and Macay grading)	6.9±5.4	7.5±5.9	0.65
Type of sinus affected*			
Pansinusitis	29	29	0.70
Maxillary	16	20	
Ethmoid	3	1	
Frontal	1	0	
Sphenoidal	0	1	
Maxillary+ethmoid	7	5	
Maxillary+frontal	0	1	
Maxillary+sphenoidal	0	1	
Ethmoid+frontal	2	2	
Sphenoidal+frontal	2	0	
AEC-Biomarkers	300,205	337.5,172	0.95
Rhinoscopy	5.4±1.9	5.3±1.9	0.89
GAI	3.6±0.6	3.5±0.5	0.32
GAP	3.7±0.6	3.6±0.6	0.27
Nasal signs and symptoms present#			
Nasal mucosa colour			
Nasal Mucosa (erythematous)	44 (74.6)	45 (80.4)	0.53
Nasal mucosa Swelling/oedema			
Either nostril	52 (96.4)	52 (98.2)	0.83
Left nostril	52 (94.5)	49 (96.1)	
Nasal secretion consistency			
Thin	16 (27.1)	16 (28.6)	0.23
Thick	40 (67.8)	40 (71.4)	
Crusty	3 (5.1)	0 (0.0)	
Nasal secretion			
Moderate	32 (54.2)	28 (50.0)	0.82
Profuse	10 (16.9)	12 (21.4)	
Discolored	46 (78.0)	44 (80.0)	-
blood streaked	8 (13.6)	8 (14.3)	-
Nasal obstruction	46 (76.6%)	48 (80%)	0.65
Face tenderness	54 (91.5)	52 (92.9)	0.56
Post nasal dripping	55 (93.2)	51 (91.1)	0.56
Dental abnormalities	15 (25.4)	15 (26.8)	-
Halitosis	30 (50.8)	26 (46.4)	-

*n, #mean±SD (standard deviation); median, inter quartile range. TSS: Total symptom score, SNOT-22: Sino-nasal outcome test, CT: Computed tomography, GAI: Global assessment by investigator, GAP: Global assessment by patient, AEC: Absolute eosinophilic count

Statistical methods

Efficacy data were analysed using the intention-to-treat principle. After confirming the normal distribution of the outcome, variable parametric tests were applied. Continuous variables are presented as mean ± SD, *n* (%) and median (interquartile range [IQR]) for baseline characteristics, mean ± SE, n (%) or median (IQR) for outcome variables. Missing values were handled with the last observation carry forward method. For the primary outcome measure (TSS), the area under the curve was calculated following the trapezoid rule at 3 months.[24] Analysis was performed using the Statistical Package for the Social Sciences, version 20.0 (IBM Corp., IBM SPSS Statistics for Windows, Armonk, New York, USA). $P < 0.05$ was considered significant.

Results

A total of 322 patients were screened for assessing eligibility as per the inclusion and exclusion criteria, 202 patients were

excluded and 120 were enrolled. Intention to treat approach was followed using the last observation carried forward to handle the missing values. There was an attrition rate of 15% and 13% in the IH and Pl group, respectively. The flow of patients is given in Figure 1. The study covered 53.3% of males and 46.6% of females. The duration of illness was 8.9 ± 6.9 years, and 6.7 ± 6.2 years in homoeopathic group and placebo group, respectively. Table 1 shows the characteristics and clinical findings at the baseline. The groups were comparable at baseline.

Primary outcome

The AUC for TSS during 3 months was calculated in both groups. A total of six measurements fortnightly were considered. Independent *t*-test for the AUC TSS – was not statistically significant between both the groups over 90 days (IH: 1303.1 ± 612.2; Pl: 1380.1 ± 811.8; 95% CI:−336.9, 182.9; $P = 0.56$). Independent *t*-test on the absolute mean difference from baseline at time points on the 60th day (mean different = 4; 95% CI: 0.3–7.7, $P = 0.03$) and 75th day (mean different = 3.9, 95% CI: 0.1–7.5, $P = 0.04$) [Figure 2] was statistically significant.

The changes in SNOT-22 show a trend of improvement towards IH, but it was statistically insignificant at 90 days (IH: mean ± SE: 30.8 ± 2.4; Pl: mean ± SE: 27.5 ± 2.9; 95% CI: −4.1, 10.8; $P = 0.38$) [Figure 3].

Secondary outcomes

Nasal rhinoscopy showed a trend of improvement towards the IH group at day 90 (at the end of 3rd month) but was not statistically significant ($P = 0.05$). Similarly, the changes at 6 months were also non-significant ($P = 0.66$). The CT scan changes in sinuses with LMS showed no differences between the groups (difference: −0.48, 95% CI, $P = 0.07$). The percentage of patients in whom there was complete resolution in sinuses in CT scan at day 90 was higher in the IH group, that is, 25.6% ($n = 11$) out of 43 reported and 11.1% ($n = 05$) out of 45 reported in the Pl group, but the results were statistically non-significant (Chi-square = 3.09, $P = 0.07$).

AEC indicated a non-significant difference between the groups ($P = 0.09$) at the end of 90 days [Table 2].

IH showed statistically significant improvement compared to placebo in PtGBA and by the investigator in the 3rd month ($P < 0.001$) and in the 6th month by the patient ($P = 0.05$) and by the investigator ($P = 0.05$), respectively [Table 2].

The AE-CRS at the end of 180 days between IH (mean ± SE:0.9 ± 0.2) and placebo (mean ± SE: 0.9 ± 0.2) was not significant (95% CI = −0.58, 0.47, $P = 0.85$).

The medicines prescribed and indicated at baseline are shown in Table 3. A total of *20* medicines were prescribed. In IH group, *Silicea* ($n = 15$), *Lycopodium clavatum* ($n = 8$), *Calcarea carbonica* ($n = 7$) *Pulsatilla nigricans* ($n = 6$), *Kali bichromicun* ($n = 5$), *Phosphorus* ($n = 4$), *Natrum muriaticum* ($n = 3$), *Arsenicum album* ($n = 2$), *Ignatia amara* ($n = 2$), *Kali ioddatum* ($n = 2$), *Sulphur* ($n = 2$) and *Mercurius solubilis, Nux vomica, Sepia* and *Staphysagria* to one each were prescribed. While in the pl. group, the medicines prescribed were: *Silicea* ($n = 14$), *L. clavatum* ($n = 7$), *P. nigricans* ($n = 7$), *Phosphorus* ($n = 5$), *N. muriaticum* ($n = 5$), *Nux vom.* ($n = 3$), *Staph.* ($n = 3$), *Kali chromium* ($n = 3$), *C. carbonica* ($n = 2$) and *A. album* ($n = 2$), *Sulphur* ($n = 2$), *Kali carbonicum* ($n = 2$), *Kali iodatum, Graphites, Lachesis, Nitric acid* and *Thuja* to one each. The pattern of prescription was similar in both groups.

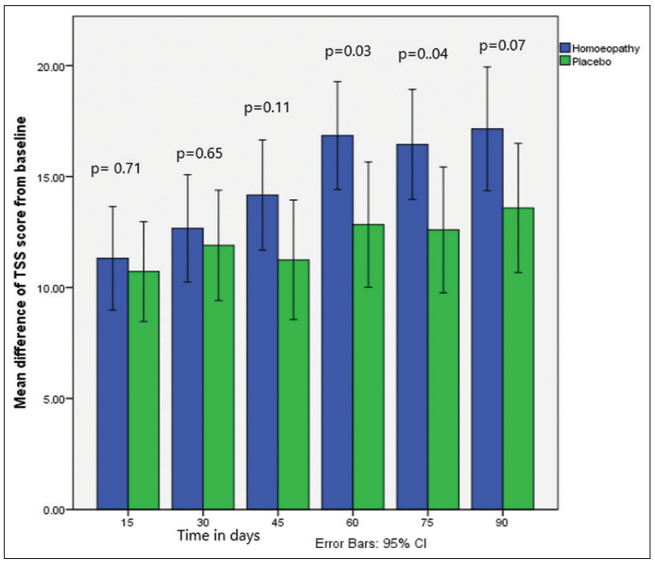

Figure 2: Changes in total symptom score score over 3 months

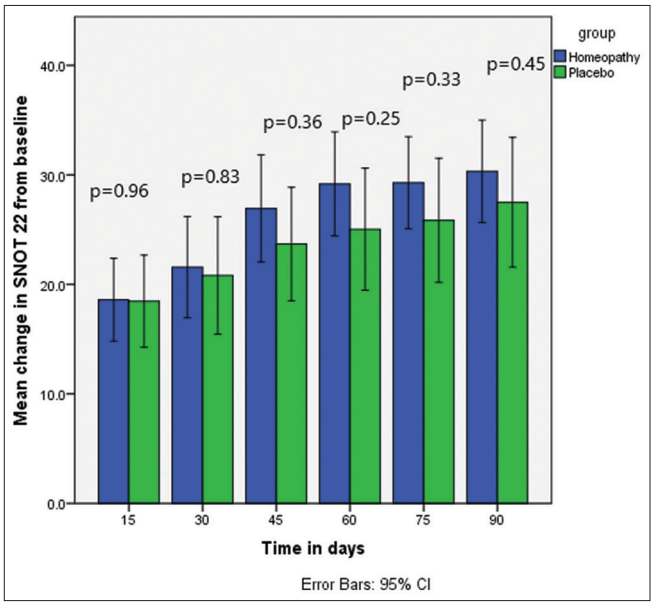

Figure 3: Changes at different time points in sino-nasal outcome test-22

Adverse events

No harmful effects, unintended effects, homoeopathic aggravations or serious adverse events were reported from either group of patients during the intervention period. Two adverse events were reported, one each in the IH for fatigue and

Table 2: Primary and secondary outcomes

Variable	IH	Pl	Mean different between the groups	95% CI	*P* value
TSS (AUC) over 90 days	1303.1±79.0	1380.1±104.8	−77	−336.9, 182.9	0.56*
TSS-absolute change					
0–30	12.6±1.2	11.9±1.2	0.7	−2.6 to 4.9−0.7	0.65
0–45	14.1±1.2	11.2±1.2	2.9	to 6.5	0.11
0–60	16.8±1.3	12.8±1.4	4.0	0.3 to 7.7	**0.03***
0–75	16.4±1.2	12.6±1.4	3.8	0.1 to 7.5	**0.04***
0–90	17.1±1.3	13.5±11.2	3.6	0.4 to 7.5	0.79
SNOT (change 0–90)	30.8±2.4	27.5±2.9	3.3	−4.1, 10.8	0.38*
SNOT (Change 0–180)	35.9±2.5	33.5±3.0	2.4	−5.3, 10.2	0.57*
CT-score (change 0–90)	2.1±0.6	2.6±0.6	-0.5	−2.4, 1.4	0.61*
CT complete resolution	11 (25.6)	05 (11.1)	-	-	0.07₸
CT partial/no resolution	32 (77.4)	40 (88.9)	-		
Rhinoscopy (change 0–90)	3.2±0.3	2.3±0.3	0.9	−0.0, 1.8	0.05*
Rhinoscopy at (change 0–180)	3.5±0.3	3.3±0.3	0.2	−0.7, 1.1	0.66*
AEC (change 0–3)	0.00, 166.5	30, 152.50	-	-	0.09¶
PhGBA (change 0–3)	1.4±0.1	0.8±0.1	0.6	0.27, 0.86	**0.0001***
PhGBA (change 0–6)	1.3±0.2	0.9±0.1	0.4	−0.00, 0.84	0.05*
PtGBA (change 0–3)	1.4±0.1	0.9±0.1	0.5	0.27, 0.91	**0.0001***
PtGBA (change 0–6)	1.4±0.1	0.8±0.2	0.6	0.14, 0.98	**0.01***
No. of AE-CRS at 6th month	0.9±0.2	0.9±0.2	0.0	−0.58, 0.47	0.85*

*Independent *t*-test, Mann whitney U-test, ₸Chi square was applied. Bold indicates statistically significant at $P<0.05$. Values are presented in mean±SE (standard error); median, inter quartile range, TSS: Total symptom score, SNOT-22: Sino-nasal outcome test, CT: Computed tomography, AEC: Absolute eosinophilic count, AE-CRS: Acute exacerbation - chronic rhinos-sinusitis, AUC: Area under the curve, PtGBA: Global assessment by the patient, PhGBA: Global assessment by the physician

Table 3: Medicines prescribed in the study

S. No.	Name of medicine	Total	Homoeopathy	Placebo
1.	*Silicea*	29	15	14
2.	*Lycopodium clavatum*	15	8	7
3.	*Pulsatilla nigricans*	13	6	7
4.	*Calcarea carbonica*	9	7	2
5.	*Phosphorus*	9	4	5
6.	*Kali Bichromicum*	8	5	3
7.	*Natru, muriaticum*	8	3	5
8.	*Arsenicum album*	4	2	2
9.	*Nux vomica*	4	1	3
10.	*Staphysagria*	4	1	3
11.	*Sulphur*	4	2	2
12.	*Kali iodatum*	3	2	1
13.	*Ignatia amara*	2	2	0
14.	*Kali carbonicum*	2	0	2
15.	*Graphites*	1	0	1
16.	*Lachesis*	1	0	1
17.	*Mercurius solubilis*	1	1	0
18.	*Nitricum acidum*	1	0	1
19.	*Sepia*	1	1	0
20.	*Thuja occidentalis*	1	0	1

in the Pl group for cephalgia. Both participants took analgesics for the relief of symptoms.

Discussion

This double-blind, randomised and controlled trial with IH versus placebo conducted on 120 patients showed significant improvement in the PtGBA as well as the investigator (physician). The study also reflected small though non-significant differences in the TSS, SNOT-22 scores, CT scan and rhinoscopy. The treatment with IH followed the classical method of homoeopathic prescription. Hahnemann's latest Q potencies[25] or renewed dynamised potencies as mentioned in his 6th edition of Organon were used for the treatment. The pharmacists and investigators were given training on the study process and conduct before its initiation. The randomisation chart was accessible to the pharmacist and chief coordinator of the study who were not involved directly in the interrogation or prescription to the patient. After acquiring the data in predesigned excel format from the study sites, the codes were concealed until statistical analysis was done by the biostatistician, for inferences.

A recent study by Mishra *et al.*[26] also showed similar results when using SNOT-20, NRS scale for symptoms and EQ-5D-5L questionnaire as the outcome measures wherein the results were insignificant with a sample size of 62, whereas, in our study, we used the latest version of SNOT-22 which included two important symptoms nasal obstruction and loss of smell,[27] TSS based on the European position paper on rhinosinusitis and nasal polyps 2007.[2] Our study also focused on CT scan with LMS, a validated measure and sensitive to perceive the changes in CRS radiologically.[23]

Although the difference as per the protocol-defined outcomes has not been achieved in all aspects, *post hoc* analysis at different time points has shown a difference in the TSS score at the 60th and 75th day of treatment showing

a trend in the treatment differences. There was a significant difference in the perception by both the patient and physician in their symptomatic improvement at the 3rd and 6th month, respectively, which supports the positive effect of homoeopathy. This was also observed in studies by Witt *et al.*[14] and Nayak *et al.,*[15] but the latter studies were cohort studies with one group of patients.

Nayak *et al.*[15] in their study reported 23% of patients whose X-ray findings became normal after treatment for 3 months. Similarly, our study also reports 25.6% in the homoeopathy group and 11.1% in the control arm.

The 20 medicines prescribed in our study go well with the suggestions by Witt *et al.*, Nayak *et al.* and Peters *et al.*[14,15,28] A clinically significant improvement in both treatment groups as per the predefined protocol has also been reported in other trials of homoeopathy.[29,30]

It was observed that improvements took place within the first 3 months of homoeopathic treatment, and they were still seen afterwards which was found in the study on chronic sinusitis by Witt *et al*.[14] However, the consistent improvement was not observed in this study. This can be due to maintaining cause or exciting cause that may have hampered the effectiveness of the intervention. Further, it may be noted that being a short-term study of 6 months, seasonal variations could not be recorded or adjusted during analysis.

Conclusion

IH has shown positive directions but with non significance statistically in the treatment of CRS. Further trials are warranted.

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Declaration of interest

The authors declare no conflicting of interest.

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Conflicts of interest

None declared.

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Un essai randomisé, en double aveugle, contrôlé par placebo et à bras parallèles pour évaluer l'effet des médicaments homéopathiques sur la rhinosinusite chronique

Contexte: La rhinosinusite chronique (SRC) est un problème de santé important qui a une incidence sur la qualité de vie liée à la santé. **Objectifs:** Cette étude évalue l'efficacité de l'homéopathie individualisée (IH) dans la puissance LM dans le SRC. **Méthodes:** Un essai randomisé, en double aveugle et contrôlé par placebo sur des patients atteints de SRC a été entrepris dans quatre instituts, de juillet 2012 à décembre 2013. Les participants éligibles ont été randomisés pour recevoir l'IH dans les puissances LM (n = 60) ou un placebo similaire (n=60). Le résultat principal était les modifications du score total des symptômes (TSS) (aire sous la courbe) et du test de résultat nasal sinusal 22 (SNOT-22) sur trois mois. L'approche en intention de traiter a été utilisée pour les analyses. **Résultat:** l'ASC du TSS sur trois mois était inférieure dans le groupe homéopathie par rapport au groupe placebo, mais elle était statistiquement non significative (IH: 1 303,1 ± 612,2; P = 1 380,1 ± 811,8; IC à 95%: -336,9, 182,9 ; p = 0,56). La différence absolue de TSS par rapport au départ avait une différence statistiquement significative au jour 60 (diff. moyenne= 4 ; IC à 95 % : 0,3 à 7,7, p = 0,03) et au jour 75 (diff. moyenne= 3,8; 95%: 0,1 à 7,5 , p=0,04) favorisant l'homéopathie. L'évaluation globale par l'investigateur et le patient a montré une amélioration satisfaisante au jour 60 (moyenne diff. = 0,6, IC 95 % : 0,27 à 0,86, p = 0,0001) et (moyenne diff. = 0,5, IC 95 % : 0,27 à 0,84, p =0,0001) respectivement. Une tendance positive a été observée dans le score de rhinoscopie dans le groupe Homéopathie (moyenne diff: 0,9, IC à 95%: -0,00 à 1,8, p = 0,05). Il n'y avait pas de différence dans les scores de tomodensitométrie des sinus paranasaux. **Conclusion:** Cette étude fournit une tendance positive à l'appui de l'effet des remèdes homéopathiques sélectionnés individuellement chez les patients atteints de SRC et justifie une évaluation plus approfondie.

Eine randomisierte, doppelblinde, placebokontrollierte, parallel angelegte Studie zur Bewertung der Wirkung homöopathischer Arzneimittel bei chronischer Rhinosinusitis

Hintergrund: Chronische Rhinosinusitis (CRS) ist ein bedeutendes Gesundheitsproblem, das die gesundheitsbezogene Lebensqualität beeinträchtigt. **Zielsetzungen:** In dieser Studie wird die Wirksamkeit der individualisierten Homöopathie (IH) in LM-Potenz bei CRS untersucht. **Methoden:** Eine randomisierte, doppelblinde, placebokontrollierte Studie an Patienten mit CRS wurde von Juli 2012 bis Dezember 2013 an vier Instituten durchgeführt. Die in Frage kommenden Teilnehmer wurden randomisiert und erhielten entweder IH in LM-Potenzen (n=60) oder ein vergleichbares Placebo (n=60). Primärer Endpunkt waren Veränderungen im Total Symptoms Score (TSS) (Fläche unter der Kurve) und im Sinus Nasal Outcome Test 22 (SNOT-22) über drei Monate. Für die Analysen wurde der Intention-to-treat-Ansatz verwendet. **Ergebnis:** Die TSS-AUC über drei Monate war in der Homöopathiegruppe geringer als in der Placebogruppe, aber statistisch nicht signifikant (IH: 1303,1±612,2; P= 1380,1±811,8; 95% CI: -336,9, 182,9; p=0,56). Die absolute Differenz im TSS gegenüber dem Ausgangswert wies am Tag 60 (mittlere Differenz = 4; 95% CI: 0,3 bis 7,7, p=0,03) und am Tag 75 (mittlere Differenz =3,8;95%: 0,1 bis 7,5, p=0,04) einen statistisch signifikanten Unterschied zugunsten der Homöopathie auf. Die Gesamtbeurteilung durch den Prüfer und den Patienten zeigte eine zufriedenstellende Verbesserung an Tag 60 (mittlerer Unterschied =0,6, 95% CI: 0,27 bis 0,86, p=0,0001) bzw. (mittlerer Unterschied = 0,5, 95% CI: 0,27 bis 0,84, p=0,0001). Ein positiver Trend wurde beim Rhinoskopie-Score in der Homöopathie-Gruppe beobachtet (mittlerer Unterschied: 0,9, 95% CI: -0,00 bis 1,8, p=0,05). Bei den CT-Scans der Nasennebenhöhlen gab es keinen Unterschied. **Schlussfolgerung:** Diese Studie liefert einen positiven Trend zur Unterstützung der Wirkung individuell ausgewählter homöopathischer Mittel bei Patienten mit CRS und rechtfertigt eine weitere Bewertung.

क्रोनिक राइनो साइनुसाइटिस में होम्योपैथिक दवाओं की प्रभावशीलता का आकलन करने हेतु एक यादृच्छिक, डबल-ब्लाइंड, प्लेसिबो-नियंत्रित, पैरेलल-आर्म परीक्षण

पृष्ठभूमि: क्रोनिक राइनो साइनुसाइटिस (सीआरएस) जीवन की स्वास्थ्य संबंधी गुणवत्ता को प्रभावित करने वाली एक गंभीर स्वास्थय समस्या है। **उद्देश्य:** इस अध्ययन में सीआरएस में व्यक्तिगत रूप से चयनित होम्योपैथी (आईएच) की एलएम पोटेंसी की दवाओं की प्रभावशीलता का मूल्यांकन किया गया है। **विधि:** जुलाई 2012 से लेकर दिसंबर 2013 तक चार संस्थानों में सीआरएस से ग्रस्त रोगियों पर यादृच्छिक, डबल-ब्लाइंड, प्लेसीबो-नियंत्रित परीक्षण किया गया। योग्य प्रतिभागियों को एलएम पोटेंसी की आईएच वर्ग (n = 60) या समरूप प्लेसीबो वर्ग (n = 60) में अनियमित किया गया था। कुल लक्षण स्कोर (टीएसएस) (वक्र के अंतर्गत क्षेत्रफल, एयूसी) और साइनस नेसल परिणाम परीक्षा 22 (SNOT-22) में तीन महीनों के दौरान आने वाले बदलाव मुख्य परिणाम थे। विश्लेषण के लिए 'इंटेनशन टू ट्रीट' तरिके का उपयोग किया गया। **परिणाम:** प्लेसीबो वर्ग की तुलना में होम्योपैथी वर्ग में तीन महीनों के दौरान टीएसएस एयूसी कम हुआ, लेकिन सांख्यिकीय रूप से महत्वहीन रहा (आईएच: 1303.1±612.2; P= 1380.1±811.8; 95% CI: -336.9, 182.9; p=0.56)। आधार रेखा से टीएसएस में पूर्ण अंतर 60वें दिन (औसत अंतर= 4; 95% CI: 0.3 से 7.7, p=0.03) और 75वें दिन (औसत अंतर =3.8;95%: 0.1 से 7.5, p=0.04) सांख्यिकीय रूप से महत्वपूर्ण रहा जो होम्योपैथी के पक्ष में रहा। वैश्विक जाँचकर्ता और रोगी मूल्यांकन में 60वें दिन और 75वें दिन का सकारात्मक सुधार क्रमशः (औसत अंतर =0.6, 95% CI: 0.27 से 0.86, p=0.0001) और (औसत अंतर = 0.5, 95% CI: 0.27 से 0.84, p=0.0001) देखा गया। होम्योपैथी वर्ग के राइनोस्कोपी स्कोर में एक सकारात्मक रुझान देखा गया (औसत अंतर: 0.9, 95% CI: -0.00 से 1.8, p=0.05)। पैरानेसल साइनस के CT स्कैन स्कोर में कोई अंतर नहीं पाया गया। **निष्कर्ष:** यह अध्ययन सीआरएस से ग्रस्त रोगियों में व्यक्तिगत रूप से चयनित होम्योपैथिक उपचार के प्रभाव का समर्थन करने के लिए एक सकारात्मक रुझान प्रदान करता है और आगामी मूल्यांकन सुनिश्चित करता है।

Un ensayo aleatorizado, doble ciego, controlado con placebo, de brazo paralelo para evaluar el efecto de los medicamentos homeopáticos en la rinosinusitis crónica

Fondo: La rinosinusitis crónica (CRS) es un problema de salud significativo que afecta la calidad de vida relacionada con la salud. **Objetivos:** Este estudio evalúa la eficacia de la homeopatía individualizada (IH) en la potencia de LM en CRS. **Métodos:** Se realizó un ensayo aleatorizado, doble ciego, controlado con placebo en pacientes con CRS en cuatro institutos, desde julio de 2012 hasta diciembre de 2013. Los participantes elegibles fueron asignados al azar a IH en potencias LM (n=60) o un placebo similar (n=60). El resultado primario fueron los cambios en la puntuación total de síntomas (TSS) (área bajo la curva) y en la prueba de resultado nasal sinusal 22 (SNOT-22) durante tres meses. Para los análisis se utilizó el enfoque por intención de tratar. **Resultado:** El AUC de TSS durante tres meses fue menor en el grupo de homeopatía en comparación con el grupo de placebo, pero fue estadísticamente insignificante (IH: 1303.1±612.2; P= 1380,1±811,8; 95% CI: -336,9, 182,9; p=0,56). La diferencia absoluta en el TSS desde el inicio tuvo una diferencia estadísticamente significativa en el día 60 (diferencia media = 4; 95% CI: 0,3 a 7,7, p=0,03) y día 75 (diferencia media = 3,8; 95%: 0,1 a 7,5, p=0,04) favoreciendo la homeopatía. La evaluación global realizada por el investigador y el paciente mostró una mejoría satisfactoria en el día 60 (diferencia media = 0,6, 95% CI: 0,27 a 0,86, p= 0,0001) y (diferencia media = 0,5, 95% CI: 0,27 a 0,84, p=0,0001) respectivamente. Se observó una tendencia positiva en la puntuación de la rinoscopia en el grupo de homeopatía (diferencia media: 0,9, 95% CI: -0,00 a 1,8, p=0,05). No hubo diferencias en las puntuaciones de CT de los senos paranasales. **Conclusión:** Este estudio proporciona una tendencia positiva para apoyar el efecto de los remedios homeopáticos seleccionados individualmente en pacientes con CRS y justifica una evaluación adicional.

评估顺势疗法药物对慢性鼻窦炎疗效的随机、双盲、安慰剂对照、平行臂试验.

背景：慢性鼻窦炎（CRS）是影响健康相关生活质量的重要健康问题。 **目的：**本研究评估个体化同种病（IH）对CRS患者LM效力的影响。 **方法：**2012年7月至2013年12月，在四个研究所对CRS患者进行了随机、双盲、安慰剂对照试验。符合条件的参与者被随机分配到LM效力的IH组（n=60）或类似的安慰剂组（n=60）。主要结果是三个月内总症状评分（TSS）（曲线下面积）和鼻窦鼻结果测试22（SNOT-22）的变化。分析采用意向治疗法。**结果：**与安慰剂组相比，顺势疗法组三个月的TSS AUC较低，但无统计学意义（IH:1303.1±612.2；P=1380.1±811.8；95%CI:-336.9182.9；P=0.56）。在第60天（平均差值=4；95%CI:0.3-7.7，P=0.03）和第75天（平均差=3.8；95%CI:0.1~7.5，P=0.04），TSS与基线的绝对差异具有统计学意义赞成同性恋。研究者和患者的总体评估分别在第60天显示了令人满意的改善（平均差异=0.6，95%CI:0.27至0.86，p=0.0001）和（平均差异=0.05，95%CI:0.27~0.84，p=0.0001。 同源病组的鼻镜检查评分呈阳性趋势（平均差异：0.9，95%可信区间：-0.00至1.8，p=0.05）。鼻窦CT扫描评分无差异。 **结论：**本研究提供了一个积极的趋势来支持个体选择的顺势疗法治疗CRS患者的效果，并值得进一步评估.