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CLINICAL RESEARCH

A multicentric open clinical trial to evaluate the usefulness of 13 predefined homoeopathic medicines in the management of acute rhinitis in children*

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Aims: The study aimed to evaluate the effect of a group of homoeopathic medicines in children with acute rhinitis.

Materials and Methods: In this multi-centric open clinical trial, a total of 784 children (408 males; 384 females) aged 6 months to 15 years, presenting symptoms of acute rhinitis were enrolled from 7 Institutes/ Units under the Central Council for Research in Homoeopathy (India). Symptoms were assessed using an acute rhinitis symptom score (ARSS). A total of 13 homoeopathic medicines were shortlisted after repertorizing the nosological symptoms of acute rhinitis in children and the results were analyzed. The medicines were prescribed in dilution 6c (10^{-12}) and doses were repeated from few minutes to few hours as per the need of the case. Appearance of any change (improvement or worsening) was followed by placebo / change in dilution or change in medicine according to the response of the patient. The follow up period was up to the 7th day of illness.

Results: Out of 784 children enrolled, 638 children were followed up and analyzed. A significant change in the score from the baseline ($p<0.05$) was observed. Twelve medicines were found to be useful in 638 children suffering from acute rhinitis and among them *Nux-v* (n=109), *Merc* (n=106) and *Bell* (n=88) were the most useful. No complications were observed during the treatment. Adverse events in the form of hyperpyrexia were observed in 2 children only.

Conclusion: This study indicates the usefulness of homoeopathic medicines in the management of acute rhinitis of children; controlled studies are needed to investigate their efficacy and effectiveness.

Keywords: observational study; homoeopathy; acute rhinitis; children

Introduction

Acute rhinitis in children is classified in ICD-10 under item J00.[1] Rhinitis has been defined by the Joint Task Force Parameters on allergy, asthma, and immunology as the inflammation of the mucous membrane lining of the nose, characterized by nasal congestion, rhinorrhea, sneezing, itching of the nose, and postnasal drainage.[2] Generally, the severity of the symptoms increases rapidly, peaks within 2-3 days after infection and decreases soon after. The mean duration of common cold is 7-10 days, but in a proportion of patients some symptoms can still be present after 3 weeks.[3]

Acute respiratory infections account for 20-40% of outpatient and 12-35% of inpatient attendance in a general hospital.[4] There is not enough evidence of important benefits from the treatment of upper respiratory tract infections with antibiotics to warrant

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their routine use in children or adults and there is a significant increase in adverse effects associated with antibiotic use in adult patients.[5-7] Despite the great advances in contemporary medicine, the common cold continues to be a great burden on society in terms of human suffering and economic losses.[4] They may appear quite bearable to the non-sufferer, but emerging data suggest that a measurable decline in health status may occur.[8]

Homoeopathic medicines are found to be effective in variety of respiratory complaints in almost all age groups.[9,10] Riley's controlled trials using homoeopathic immunotherapy in inhalant allergy as a model has evidenced that homoeopathy differed significantly from placebo.[11] For this reasons, a multi-centric observational study was carried out to evaluate the role of 13 predefined homoeopathic medicines in the management of acute rhinitis in children and to assess the degree of intensity of symptoms amenable to homoeopathic treatment.

Materials and Methods

Study design and setting

This was a multicentric open clinical trial conducted at Central Research Institutes, Noida (Uttar Pradesh), & Kottayam (Kerala), Regional Research Institutes, Imphal (Manipur) & Shimla (Himanchal Pradesh), Clinical Research Units, Agartala (Tripura), Port Blair (Andaman & Nicobar Islands) & Dimapur (Nagaland) under the CCRH (henceforth Council) during the period October 2005 - June 2008.

Seven investigators who are trained homoeopathic doctors with experience of more than 5 years were involved to prescribe medicines for children suffering from acute rhinitis. The study protocol was in accordance with the Helsinki declaration on human experimentation and Good Clinical Practices for Clinical Research in India.[12,13] Ethical clearance was obtained from Council's Ethical Committee. Prior training was given to all participating investigators regarding the study protocol.

Patient population

Seven hundred eighty four children (404 male; 380 female) older than 6 months and younger than 15 years with acute rhinitis of less than 7 days duration were eligible to participate. The procedures for enrollment and follow up are described in flow-chart (Fig. 1). Written informed consent was obtained from parent/guardian before enrolling child in the study.

Selection of 13 predefined trial medicines

Thirteen predefined homoeopathic medicines were selected by repertorising the nosological symptoms[14] of acute rhinitis using Complete Repertory in Cara professional software.[15] The rubrics *'Coryza, General, children, in', 'Nose - Discharge, watery' and 'Nose - Inflammation'* were taken as eliminating symptoms,[16] the first 13 medicines covering all the eliminating rubrics irrespective of their gradation were included in the study. These medicines were: *Aconitum napellus, Belladonna, Calcarea carbonica, Carbo vegetabilis, Chamomilla, Dulcamara, Elaps corallinus, Hepar sulphur, Kalium bichromicum, Mercurius solubilis, Nux vomica, Pulsatilla nigricans* and *Sulphur.* The trial medicines were prepared by a GMP (Good Manufacturing Practices) certified pharmacy and approved by the Scientific Advisory Committee of the Council.

Intervention

A repertorization chart comprising 21 common symptoms of acute rhinitis with the respective gradation of the trial medicines as mentioned in Complete Repertory was provided to the investigators. From this repertorization chart, the symptoms present in the patient were highlighted to sort out the group of top ranking medicines. Full scope was given for individualization of patient and the final selection of the medicine was made after consultation of the homoeopathic materia medica. Cases which required medicines other than the trial ones were treated in the general outpatient clinic and not included in the study. As this was an open label study, prescription was known to both investigators and the parents of the children.

All medicines were prescribed in dilution 6c (10^{-12}) and were repeated every few minutes to hours depending on the frequency, intensity and duration (FDI) of the symptoms, until perceptible change appeared [improvement in sign(s) and symptom(s), appearance of new symptoms, worsening of sign(s) and symptom(s)]. Appearance of any change was immediately followed by placebo/ change in dilution/ change in remedy, according to response. All follow up action was taken as per guidelines in Hahnemann[17] and Kent.[18] In our understanding, this includes ceasing medication and prescribing inert globules (placebo) after the patient began presenting signs of

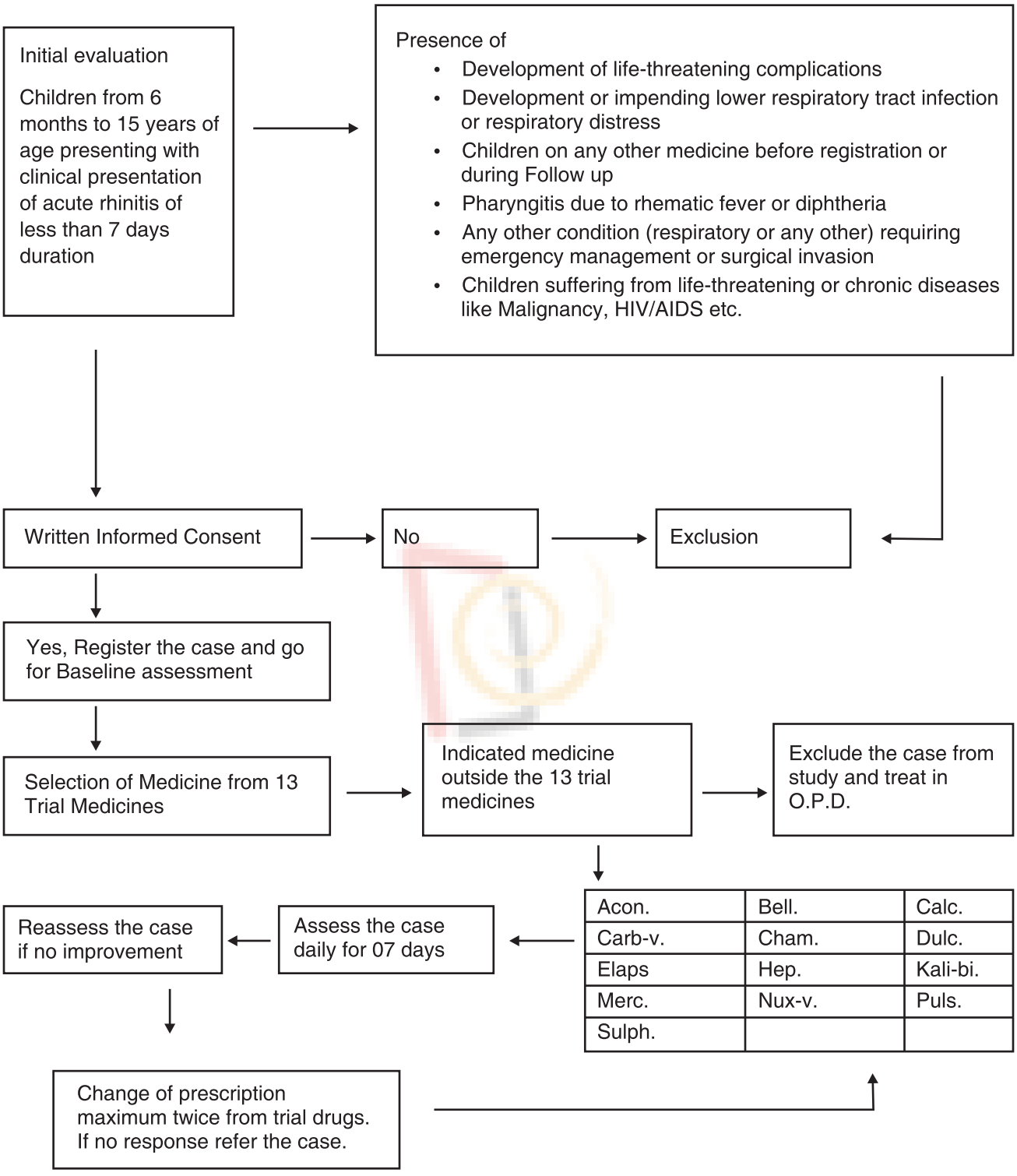

Figure 1-Flow chart of the study design

improvement. All patients were called for daily follow-up and assessment for each patient was made on the seventh day of suffering irrespective of the continuity of treatment. In the eventuality of any emergency, patients were referred for emergency treatment. As a part of non-medical management all the guardians/parents were advised to make their children drink plenty of warm fluids, make steam inhalation once a day, do deep breathing exercises and avoid swimming; no patient was advised to use any vitamins or natural supplements.

Assessment and analysis of data

To quantify the exact severity of each symptom of acute rhinitis, the Council developed a 16-point acute rhinitis symptom score (ARSS) (Table 1) which was

Table 1-Acute Rhinitis Symptoms Score (ARSS)

Symptoms/signs	Score				
	0	1	2	3	4
Running nose/nasal discharge	Absent	Watery (thin)	Mucoid (thick, white)	Mucopurulent (yellow, green)	
Discharge (Sensation)	Absent	Bland	Acrid		
Discharge (quantity)	Absent	Scanty	Copious		
Sneezing	Absent	Occasional	Infrequent	Constant	
Nasal obstruction (frequency)	Absent	Occasional	Always		
Nasal obstruction (Side)	Absent	Unilateral	Bilateral compelled to breath through mouth	Post nasal dripping	
Irritation in nose and eyes	Absent	Itching	Burning	Pain	
Irritation in throat	Absent	Itching	Burning	Pain	
Lachrymation/ watering eyes (Quality)	Absent	Bland	Acrid		
Lachrymation/ watering eyes (Quantity)	Absent	Occasional	Always		
Malaise	Absent			Present	
Congestion of nasal mucosa	Absent			Swollen, red	
Congestion of nasal turbinates	Absent			Swollen, red	
Fever	Abse nt	Mild (97°C - 99°C)	Moderate (99°C - 101°C)	Severe (101°C -105°C)	Hyperpyrexia (⩾105°C)
Headache	Absent	Present			
Anosmia	Absent	Present			

approved by Council's Scientific Advisory Committee. The total score was measured at baseline and at each follow up. The intensity of rhinitis which was measured by ARSS was divided into mild (2-13); moderate (14-25); severe (26-40). In children who could not be followed up to 7th day of illness due to a too early relief of symptoms after start of treatment, the last assessed value was carried forward up to the 7th day of illness.

Primary outcome measure was change in ARSS score. Improvement (impr) was calculated using formula:

$$\text{impr} = \frac{\text{baseline score-score at end}}{\text{baseline score}} \times 100$$

Changes 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 symptoms score).

Descriptive statistical characteristics and comparative analysis were made using SPSS (Statistical Package for Social Science) Version 16. For normally distributed data, comparisons of score at entry with score at end were made using paired t test, and one-way/single-factor ANOVA was used to analyze improvement between the groups. Wilcoxon rank sum test was used to compare the non-parametric data of individual symptoms, $p < 0.05$ was considered as significant.

Results

Over 2 years and 8 months, 784 children from 7 different Institutes / Units under the Council were enrolled, out of whom 54 were lost to follow up, 90 were excluded due to non-adherence to the protocol and 2 were referred due to hyperpyrexia. 638 children (male 334; female 304) were followed up and studied. Demographic data of children at baseline are described in Table 2. Mean age of children less than 1 year was 7.5±3.2 months and that of children above 1

Table 2-Baseline details of children in the study

	Study group (n=638)	Mean ±SD	%
Institutes/ Units			
• CRI, Noida	105		16.5
• RRI, Kottayam	105		16.5
• RRI, Shimla	20		3.1
• RRI, Imphal	109		17.1
• CRU, Agartala	158		24.8
• CRU, Port Blair	97		15.2
• CRU, Dimapur	44		6.9
Sex (Male)	334		52.4
(Female)	304		47.6
Age (<1 yr)	55	7.5 ±.3.2 months	
(>1yr)	583	6.6 ± 3.4 years	
Days of suffering from rhinitis			
• 1day	45		7.1
• 2 days	266		41.7
• 3 days	210	2.67±0.95	32.9
• 4 days	90		14.1
• 5 days	25		3.9
• 6 days	02		0.3
ARSS (range)			
• 2-13 (Mild)	264	9.9±2.8	41.4
• 14-25 (Moderate)	305	17.5±2.7	47.8
• 26-42 (Severe)	69	28.2±1.6	10.8

year was 6.6±3.4 years. The incidence of acute rhinitis was mostly in the group under age 5 (n=271) followed by the 6-10 years old age group (n=199), 11-15 years (n=113) and < 1 year (n=55). Various predisposing factors which triggered rhinitis in children are illustrated in Figure 2. Exposure to cold was found in 22% of the children. Exposure to dust and irregular diet triggered the least (1%) development of the same.

As shown in Table 3, 99.2% of the children presented running nose followed by sneezing (84.3%), and nasal obstruction (66.9%). A non-parametric Wilcoxon rank sum test was used to compare the symptoms before and after treatment and the results were found to be statistically significant ($p < 0.05$).

Mean ARSS was analyzed before and after treatment using paired t test (Table 4). The change in the mean

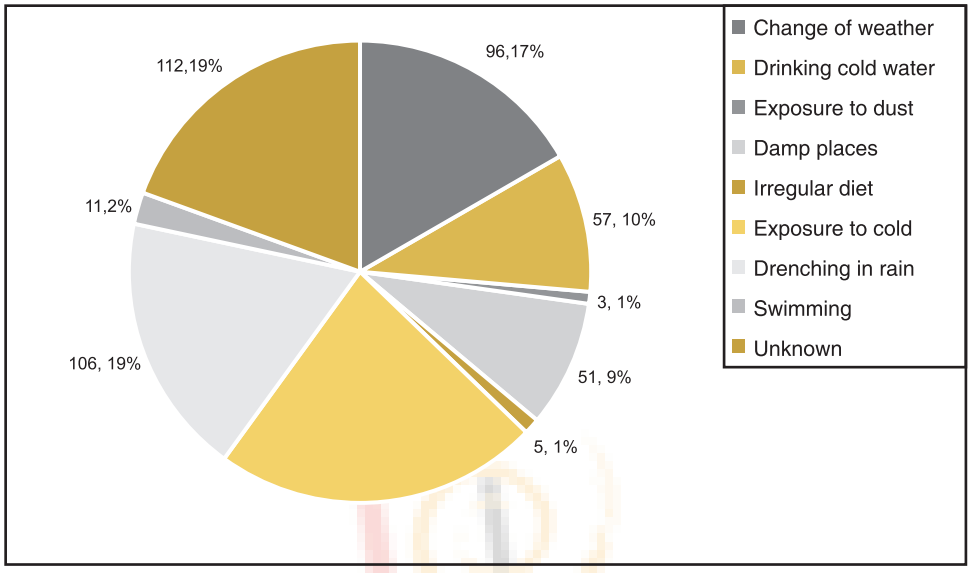

Figure 2-Predisposing factors of acute rhinitis in children

Table 3-Change in severity score of symptoms / signs in children with acute rhinitis

Symptoms/signs	n (%)	Severity score (mean± SD)		Z*
		Before	After	
Running nose	633 (99.2)	1.6 ± 0.9	0.2 ± 0.4	21.8
Discharge (sensation)	633 (99.2)	1.5 ± 0.4	0.2 ± 0.4	22.0
Discharge (quantity)	633 (99.2)	1.6 ± 0.5	0.2 ± 0.4	22.0
Sneezing	539 (84.3)	1.6 ± 0.5	0.1 ± 0.3	20.5
Nasal obstruction (frequency)	427 (66.9)	1.3 ± 0.4	0.2 ± 0.4	18.3
Nasal obstruction (side)	427 (66.9)	1.2 ± 0.4	0.1 ± 0.3	18.8
Irritation in nose and eyes	388 (60.8)	1.5 ± 0.7	0.0 ± 0.2	17.3
Irritation in throat	214 (33.5)	1.9 ± 0.9	0.9 ± 0.3	12.7
Lachrymation (quality)	204 (32.2)	1.5 ± 0.5	0.0 ± 0.1	12.8
Lachrymation (quantity)	204 (32.2)	1.1 ± 0.3	0.0 ± 0.1	13.4
Malaise	317 (49.7)	3.0 ± 0.0	0.0 ± 0.2	17.7
Congestion of nasal mucosa	435 (68.2)	3.0 ± 0.0	0.2 ± 0.6	20.2
Congestion of nasal turbinates	51 (7.8)	3.0 ± 0.3	0.6 ± 1.2	6.2
Fever	393 (61.6)	1.5 ± 0.5	0.0 ± 0.1	17.7
Headache	308 (48.3)	1.0 ± 0.0	0.0 ± 0.1	17.4
Anosmia	74 (11.6)	1.0 ± 0.0	0.0 ± 0.2	8.5

*Wilcoxon rank sum test significant at p=0.001

score was found to be statistically significant (p <0.05; CI: 14.1-14.9). The breakup of range of intensity according to ARSS was also analyzed and the results of all the groups were statistically significant (P<0.05). One way ANOVA shows a statistically significant result between the 2 scores (before and after treatment) for all three groups, mild cases followed by the other two groups (moderate and severe), df (2,637), F=11.5, p<0.05.

Table 4-Acute rhinitis symptom score (ARSS) at entry and at end

	Mean score at entry ± SD (n)	Mean score at end ± SD (n)	p-value	95% confidence interval difference
ARSS	15.5 ± 6.3 (638)	1.0 ± 2.1 (638)	0.0001	14.0 -14.9
Range				
• Mild (2-13)	9.9 ± 2.8 (264)	0.3 ± 1.1 (264)	0.0001	9.2 - 9.9
• Moderate (14-24)	17.5 ± 2.7 (305)	1.4 ± 2.5 (305)	0.0001	15.6 -16.4
• Severe (26-42)	28.2 ± 1.6 (69)	1.6 ± 2.4 (69)	0.0001	25.9 - 27.3

Children first presented to physicians with complaints of rhinitis for a period of 2.7±0.9 days. 93.7% (n=598) of the children whose data are analyzed here were followed up for more than 2 days and only in 6.3% (n=40) children the follow up was limited to 1 day. Overall improvement in ARSS was observed within 3.5±1.2 days and complete cure in 475 children (74.4%) occurred within 3.9 ± 1.1 days of treatment.

Table 5 shows the data of 12 out of 13 medicines which were used and found to be useful in treating acute rhinitis of children: *Nux vomica 109 (17.1%), Mercurius solubilis 106 (16.6%), Belladonna 88 (13.8%), Dulcamara 66 (10.3%), Aconitum napellus 56 (8.8%), Sulphur 52 (8.2%) Calcarea carbonica 40 (6.3%), Hepar sulphur 40 (6.3%), Pulsatilla nigricans 39 (6.1%), Chamomilla 37 (5.8%), Carbo vegetabilis and Kalium bichromicum.* All these trial medicines were found to have statistically significant results at p <0.05, while *Carbo vegetabilis 3 (0.5%), and Kalium bichromicum 2 (0.3%)* though found to be significant at p=0.005 and p=0.002 respectively, however only few patients were enrolled under these medicines. *Elaps corallinus* was one of the trial medicines but it was not used at all due to lack of indications for prescription.

Medicines were given in repeated doses as per the frequency, duration, and intensity of presenting symptoms. On average, each child required 5.7±3.2 doses. We observed that 45.1% (n=298) of children

Table 5-List of useful trial medicines

Medicine	No. of patients	Percent	95% confidence interval difference*	Outcome assessment			
				Cured	Marked improvement	Moderate improvement	Mild improvement
Nux-v	109	17.1	13.66 - 16.66	87	16	6	0
Merc	106	16.6	12.57 - 14.59	77	23	6	0
Bell	88	13.8	13.69 - 15.87	57	21	9	1
Dulc	66	10.3	10.05 - 11.73	58	2	5	1
Acon	56	8.8	13.69 - 15.87	51	5	0	0
Sulph	52	8.2	13.19 - 16.99	31	13	7	1
Calc	40	6.3	13.25 - 16.64	21	10	7	2
Hep	40	6.3	12.56 - 14.08	28	9	3	0
Puls	39	6.1	17.57 - 22.12	30	8	0	1
Cham	37	5.8	11.71 - 14.88	31	6	0	0
Carb-v	3	0.5	6.46 - 12.20	3	0	0	0
Kali-bi	2	0.3	9.14 - 21.85	1	0	1	0
Total	638	100.0		475	113	44	6

*Using paired t test P value (=0.0001) was significant

required 6 doses of the prescribed medicine throughout their treatment period, 1 dose was required by 16.6% (n= 106) of children, 2 doses by 5.3% (n=34), 3 doses by 3.1% (n=20), 4 doses by 6.9% (n=44), 8 doses by 9.1% (n=58), 10 doses by 1.7% (n=11) and 12 doses by 11.4% (n=73) of children. Medicines in dilution 6c given repeatedly could alleviate the symptoms of acute rhinitis in all children. Only in 6 children, 30c dilution in single dose was required when there was no further improvement.

At the end of the study, we observed that 81.3% (n=638) of the children had improved among the 784 children enrolled. As per outcome assessment of the 638 children who were analyzed, 74.5% (n=475) were cured, 17.7% (n=113) improved markedly, 6.9% (n=44) improved moderately and only 0.9% (n=6) improved mildly. The breakup of outcome assessment under each medicine prescribed is described in Table 5. The characteristic indications of these medicines were verified and are described in Table 6.

Adverse events in the form of hyperpyrexia were observed in 2 children (less than 1%), who were referred to emergency medical care; these children were not analyzed as the patients did not adhere to treatment after the baseline assessment. General symptoms like diminished appetite, constipation,

Table 6-Characteristic indications of the trial medicines

Trial medicines	Prescribing indications
Nux vomica	*Mind*: Oversensitive *Others*: Pyrexia followed by constipation with frequent ineffectual urging for stool; headache < morning, > pressure ; loss of smell and appetite *Nose*: Discharge fluent; coryza fluent in morning or day with dryness at night; blockage of nose occurs alternately; crawling and tickling inside the nose; congestion of nasal mucosa.
Mercurius solubilis	*Others*: Fever worse at night, excessive thirst and salivation with offensive breathe; profuse perspiration; sensitive to every draught and yet < by warmth. *Nose:* Discharge watery yellowish, acrid, sneezing, nasal blockage
Belladonna	*Nose*: Discharge fluent with sudden onset, unilateral occasional nasal obstruction at night. *General*: Dryness of mouth without thirst; headache, flushed face, pyrexia, redness of eyes, face and throat.
Dulcamara	*Others:* H/o, exposure to damp, rainy weather or dwelling in the damp place, itching in both eyes worse in open air, feverish worse in the evening; greenish diarrhea, malaise. *Nose:* Running of nose, sneezing and nasal obstruction < in the rainy weather, crawling and tickling inside the nose.
Aconitum napellus	*Mind:* Restless mentally & physically. *Nose:* Fluent watery nasal discharge, thirst for large quantity of cold water < warm room and better in open air.
Sulphur	*Others:* Extremely hot and with itching eruptions or H/O of skin eruptions, craves sweets; red lips. Pyrexia, weakness with thirst and constipation. *Nose:* Nasal discharge fluent, watery, yellowish, sneezing worse in morning and evening, after bathing.
Calcarea carbonica	*Others:* Fatty, flabby, susceptible to cold; profuse sweating on head, wants to eat eggs. *Nose*: Nasal discharge is fluent, yellowish, acrid, < by cold > by hot; nasal obstruction.
Hepar sulphur	*Mind:* Sensitive, irritable *Others:* Like sour things & dislike fatty food. *Nose:* Yellowish acrid, scanty, nasal discharge < in cold, uncovering > by warm, heat. Sneezing, nasal obstruction, itching in throat with fever.

Contd. ...

Contd.

Trial medicines	Prescribing indications
Pulsatilla nigricans	*Mind:* Weeps easily *Others:* Chilly but wants cold, frontal headache < by cold; symptoms changeable; thirstlessness. *Nose:* Coryza with frequent sneezing followed by yellow-green, copious nasal discharge, < in warm room, > in open air; nasal congestion, nasal obstruction unilateral, first left then right, < evening, < change of temperature.
Chamomilla	*Others:* Fever with irritability, restless, crying always, easily annoyed, better by carrying. *Nose:* Congestion of the nasal mucosa, thin, watery, bland, copious discharge with occasional sneezing, < at night, open air.
Carbo vegetabilis	*General*: Burning in throat, body cold to touch. *Rhinitis*: Yellowish, acrid nasal discharge, sneezing
Kalium bichromicum	*Rhinitis*: Sneezing worse in early morning nasal obstruction, yellowish sticky nasal discharge

diarrhea, debility, stomatitis, vertigo along with rhinitis were also found to improve during the course of treatment for acute rhinitis.

Discussion

This multicentric observational study points out to the positive role of homoeopathic therapy in treating the common problem acute rhinitis in children. This study included children who suffered from acute rhinitis irrespective of whether it was allergic, non-allergic or infectious, based on the symptomatic picture of rhinitis, since presentation is virtually similar.[19] This study adds up, thus, to other studies worldwide agreeing with the positive role of Homoeopathy in respiratory ailments[10], vasomotor rhinitis[20], an impact on rhino-conjunctivitis quality of life questionnaire.[21]

The children in our study presented with severity of symptoms within 2-3 days (n=476) which corroborate with the findings of Heikkinen.[4] During the course of treatment the disease did not progress further and there were no complications.

Homoeopathic medicines *Calcarea carb., Dulcamara, Hepar sulph., Kali-bi., Nux-v.,* and *Sulphur* were also effective in vasomotor rhinitis as shown by Hoa.[20] In this study, *Nux-v* rated second after *Sulphur,* whereas in our study 47.5% of the children were relieved by *Nux-v,* followed by *Merc* and *Bell*. Colin[10] frequently used *Pulsatilla, Sulphur* and *Lycopodium clavatum* in respiratory allergies. We also observed that the former two medicines were useful in 14% of the children with acute rhinitis, however *Lycopodium* did not fall within our trial group of medicines. It was also found that half of the useful trial medicines in our study (*Mercurius, Belladonna, Sulphur, Calcarea, Hepar* and *Pulsatilla*) are among the top 10 most frequently prescribed remedies by Haidvogl *et al* [9] for acute respiratory and ear complaints. These findings suggest that our predefined trial homoeopathic medicines have the most pertinent role in controlling acute rhinitis.

In our study adverse events were rarely observed during the course of treatment, which agrees with Endrizi *et al* [22] and Haidvogl *et al.*[9] On the other hand, according to Aroll[6] there is insufficient evidence of benefit to warrant the use of antibiotics for upper respiratory tract infections in children and their routine use is not recommended. Homoeopathic therapy which is cost effective[23] and has rare adverse events can be used for children in primary health care where 27.5% of the people in India are below the poverty line.[24]

The main strength of this study is that it reflects the actual conditions of everyday practice and a large variety of life styles, mirroring the real conditions of the parents of children with acute rhinitis and the treatment they can expect from choosing to consult a homoeopath, in contrast to randomized trials, which create artificial situations that differ from daily practice due to highly standardized protocols and patient populations. A long-term follow up could have enabled and added the preventive aspects of recurrent upper respiratory tract infections in children.

In this observational study, although all the patients were asked to be followed daily up to the 7th day of the illness, this goal could not be achieved and it is one of the constraints of this study. Reasons were that since the patients were minors, they needed to be brought by parents/guardians. Some resided at a significant distance from the study centers, belonged to the labor class or low socio economic groups and it was

practically not possible for them to make daily visits, and some of the children needed to attend school and could not miss classes for daily assessment. Therefore, although the study has positive results, observer bias cannot be ruled out and represents another limitation.

Conclusion

This study points to the usefulness of homoeopathic medicines in the management of acute rhinitis of children, as well as the more probable homoeopathic remedies to be prescribed in this regard. This study reflect the actual conditions of everyday clinical practice, however, controlled studies should still be carried out to investigate the aspects of efficacy and effectiveness before definite conclusions can be established and recommendations be made.

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