

Research Article

Effectiveness of Characteristic Keynote Prescription of Homeopathic Medicines in Acute Nasopharyngitis in Paediatric Age Group - A Prospective, Longitudinal Observational Study

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Abstract Acute Nasopharyngitis is a common upper respiratory tract infection caused by adenoviruses, influenza, rhinovirus, parainfluenza or respiratory syncytial viruses. This prospective, longitudinal, observational study was conducted at SKHMC, Jaipur for a period of 1 year (April 2018 to March 2019), aiming to ascertain the effectiveness of characteristic keynote prescription of homeopathic medicines in the cases of Acute Nasopharyngitis in paediatric age group. In this study, 59 cases of Acute Nasopharyngitis were treated with homeopathic medicines prescribed on the basis of totality of the symptoms along with characteristic keynote symptoms. Treatment outcomes were assessed using Common Cold Questionnaire. Out of 59 patients, 36 patients (61.0%) were improved; 15 patients (25.5%) were at status quo, and 08 patients (13.5%) became worse. Maximum patients were found to be in the age group of School Age children (n=27; 45.8%) and Pre-School children (n=21; 35.6%). Males were observed to be affected more as compared to females. Paired t-test was conducted on the CCQ scores obtained before and after treatment and the result showed that p value was < 0.05 & t = 8.404, which was statistically significant which concluded that characteristic keynote prescription of homeopathic medicines was effective in cases of Acute Nasopharyngitis.

Keywords *Homeopathy; Common Cold; School age children; Observational study*

1. Introduction

Acute Nasopharyngitis or Common cold is an upper respiratory tract infection characterized by inflammation of nasopharynx caused by adenoviruses, influenza, rhinovirus, parainfluenza or respiratory syncytial viruses. These are spread by droplet infection. Predisposing factors include chilling, sudden exposure to cold air and overcrowding [1]. Acute Nasopharyngitis (Common Cold) is a viral illness in which the symptoms of rhinorrhea and nasal obstruction are prominent; systemic symptoms and signs such as headache, myalgia, and fever are absent or mild [2]. URTIs are the

most common infectious illness in the general population and are the leading cause of missed days at work or school. They represent the most frequent acute diagnosis. The incidence of the Acute Nasopharyngitis (common cold) varies by age. Rates are highest in children younger than 5 years. Children who attend school or day care are a large reservoir for URTIs, and they transfer infection to the adults who care for them. In the first year after starting at a new school or day care, children experience more infections, as do their family members. Children have about 3-8 viral respiratory illnesses per year, adolescents and adults have approximately 2-4 colds annually, and people older than 60 years have fewer than 1 cold per year [3].

Acute nasopharyngitis may last up to 14 days, with symptoms averaging 7-15 days in duration. Fever, sneezing and sore throat typically resolve early, whereas cough and nasal discharge are among the symptoms that last longest. Most URTIs are self-limited and resolve completely. As per W.H.O., common cold is a self-limited viral infection which requires only supportive care but severe complications like otitis media [4], sinusitis [4], exacerbation of asthma [4] & lower respiratory tract infections [4] may occur in children. Antibiotics should not be given as they are not effective in these cases. Symptom-based therapy represents the mainstay of URTI treatment [5].

Homoeopathy is a holistic science confirmed experimentally and clinically which boosts self - defense mechanism of the body and thereby reduces the frequency and severity of the subsequent attacks without any side-effects and also eliminates drug dependency to establish health. Scope of conventional treatment is very limited in cases of upper respiratory tract infection, especially in acute nasopharyngitis.

Considering the incidence and severe complications of upper respiratory tract infections in children and limitation of conventional treatment, this study was aimed to look into the effectiveness of characteristic keynote prescription of homoeopathic medicines in upper respiratory tract infection with emphasis on acute nasopharyngitis. The Alternate Hypothesis considered in this study was that there will be improvement in cases of acute nasopharyngitis by Characteristic Keynote Prescription of homoeopathic medicines. The objectives of this study was to clinically assess treatment outcome in cases of Acute Nasopharyngitis using Common Cold Questionnaire (CCQ) [6] as well as to observe the age incidence of Acute Nasopharyngitis in paediatric age group in Jaipur and to prepare therapeutic compendium of homoeopathic medicines for the treatment of Acute Nasopharyngitis.

2. Materials & Methods

Study setting- This study was undertaken at the O.P.D. of Swasthya Kalyan Homoeopathic Medical College & Research Centre, Jaipur.

Study duration- The duration of study was 12 months (April 2018 to March 2019), out of which first 9 months was for enrolment of the patients and their follow-ups & last 3 months was for arrangement of data, statistical analysis and concluding the study. Patients were screened on first visit as per inclusion/exclusion criteria. If the patient fulfilled the inclusion criteria, he or she was enrolled in the study. All the patients were followed-up for a period of 7 days, at an interval of 2-3 days.

Sample Size- By taking standard size of 0.4 at 90% power, sample size including drop out was 68, which was rounded-off to 70.

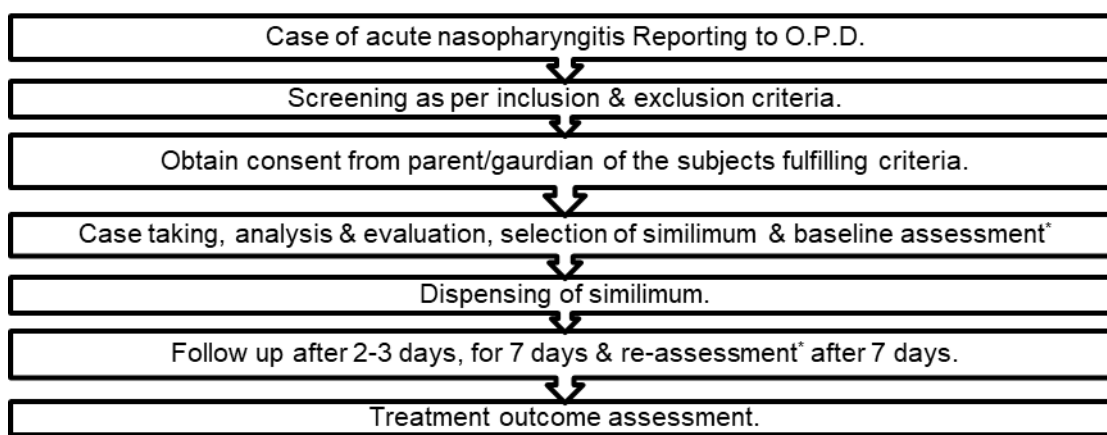
Selection of samples- Selection of cases was done randomly through coin toss method (heads-included; tails-not included) from college OPD, and written consent was taken from the parent or guardian of the patient.

Inclusion Criteria- 1. Newly diagnosed cases of Acute Nasopharyngitis seeking homoeopathic treatment & cases taking treatment from other systems of medicine with no relief. Duration of illness should not be more than 7 days. 2. Paediatric age group of both sexes.

Exclusion Criteria- 1. The case without proper follow-up and discontinuation of treatment in between the study. Such cases were dropped out. 2. Cases with complication like otitis media, epiglottitis, tracheobronchitis, Pneumonia. 3. Patient having upper respiratory tract infection secondary to systemic diseases and autoimmune disorders or patients on immune-suppressive therapy.

Study design-Prospective, Longitudinal, Observational study.

3. Brief of Procedure



*Baseline Assessment & Re-assessment:

- Common cold Questionnaire (CCQ).
- Re-assessment was done after 7 days using CCQ.

4. Intervention

- 1) **Selection of the Medicine:** - Homoeopathic Medicine was selected according to the totality of the symptoms along with characteristic keynote symptoms similarity.
- 2) **Doses and potency:** - Selection of doses and potency were done as per the susceptibility of patients. Medicine was repeated depending on the frequency & intensity of symptoms till perceptible changes appeared. Medicine was administered orally.
- 3) **Ancillary Measures:** - Medicines of other streams were restricted during the treatment. Auxiliary management was advised as per the need of each individual case, considering the instructions regarding diet and regimen in acute diseases, laid by Master Hahnemann in Section 262 & 263 of Organon of Medicine.

5. Selection of tools

- 1) Homoeopathic Case Taking Performa specially designed for this study.
- 2) Common Cold Questionnaire [4] (CCQ) was used to assess the treatment outcome in cases of Acute Nasopharyngitis.

Table I: Common Cold Questionnaire

General Symptoms	1.Fever	None	Mild	Moderate	Severe
	2.Chills	None	Mild	Moderate	Severe
	3.Muscle Pain	None	Mild	Moderate	Severe
Nasal Symptoms	1.Watery eyes	None	Mild	Moderate	Severe
	2.Runny nose	None	Mild	Moderate	Severe
	3.Sneezing	None	Mild	Moderate	Severe
Throat Symptoms	1.Sore throat	None	Mild	Moderate	Severe
Chest Symptoms	1.Cough	None	Mild	Moderate	Severe
	2.Chest Pain	None	Mild	Moderate	Severe

A 'probable' viral infection is where there are moderate symptoms noted in at least 2 of the above 4 categories or mild symptoms noted in 3 or more categories.

A 'possible' viral infection is where mild symptoms are noted in one category plus a cough.
Scoring: none = 0, mild = 1, moderate = 2, severe = 3. Total score equals the sum of all scores.

Note: Score was calculated before treatment as well as after treatment and was compared to assess the effectiveness of homoeopathic medicines. Following outcomes were assessed:

- *Improvement:* If the score was reduced by 6 or more after the treatment.
- *Status Quo:* If the score remained the same or was reduced by less than 6 after the treatment.
- *Worse:* If the score increased even after the treatment.

Data collection-Data were recorded in Homoeopathic Case Taking Proforma specially designed for this study. Data were collected after proper follow-ups. Data were maintained in both soft and hard copy.

Data analysis & Statistical techniques-Demographic data & other observations were presented using Descriptive Statistics i.e. mean, percentage, etc. Treatment outcomes were analysed using Paired t-test by using IBM SPSS 25.0.

Need of investigations-The diagnosis of the cases was done clinically by eliciting cases history and clinical findings on physical examination.

Parameter for analysing the outcome/result of this study-All the patients were followed-up for a period of 7 days at an interval of 2-3 days and score obtained from Common Cold Questionnaire was assessed before and after treatment. Following parameters were fixed according to the type of response after the treatment:

*Improvement-*If the score was reduced by 6 or more after the treatment, with relief in all signs and symptoms.

*Status quo-*No change in the score of CCQ or score was reduced by less than 6 after treatment and no specific relief in any complaints in spite of taking the medicine.

*Worse-*Increase in the score of CCQ after treatment and no improvement in the condition of the patient, instead he / she got worse.

Ethical Issues-A written consent was obtained from each participant’s parent/guardian. The study was approved by the Institutional Ethical Committee.

5. Results, Discussion and Conclusion

A total of 70 patients were enrolled in this study, out of which 11 patients were dropped-out due to missed follow-up. Observations and statistical analysis was done on 59 patients as per protocol. Out of 59 patients, maximum incidence of Acute Nasopharyngitis was observed in the School Age children (n=27; 45.8%) and Pre-School Children (n=21; 35.6%), which validates the epidemiological data, found in modern medicine literature. It was also observed that male children (n=38; 64.4%) were more affected than female children (n=21; 35.6%).

Fever is a common symptom associated with any acute infection in the body, but in case of common cold, fever is not so common. In this study, out of 59 patients, 22 patients (37.3%) had fever. Out of those 22 patients, 15 patients (25.4%) had mild fever. This observation verified modern literature which states that ‘Fever is less common in Acute Nasopharyngitis’.

15 homoeopathic medicines were used in this study according to totality of symptoms along with characteristic keynotes.

Table II: Homoeopathic Medicines used in the study

S.No.	Remedy	Total No. of Cases	Improvement	Status Quo	Worse
1.	Aconitum napellus	02 (3.3%)	00 (0%)	02 (100%)	00 (0%)
2.	Allium cepa	07 (11.9%)	04 (57%)	01 (14%)	02 (29%)
3.	Antimonium tartaricum	05 (8.5%)	04 (80%)	01 (20%)	00 (0%)
4.	Arsenicum album	10 (16.9%)	04 (40%)	04 (40%)	02 (20%)
5.	Arum triphyllum	02 (3.3%)	02 (100%)	00 (0%)	00 (0%)
6.	Belladonna	07 (11.9%)	05 (71%)	02 (29%)	00 (0%)
7.	Bryonia alba	02 (3.3%)	02 (100%)	00 (0%)	00 (0%)
8.	Calcarea carbonica	02 (3.3%)	01 (50%)	01 (50%)	00 (0%)
9	Dulcamara	04 (6.8%)	03 (75%)	01 (25%)	00 (0%)
10.	Gelsemium sempervirens	02 (3.3%)	02 (100%)	00 (0%)	00 (0%)
11.	Hepar sulphur	06 (10.2%)	05 (83%)	00 (0%)	01 (17%)
12.	Pulsatilla pratensis	05 (8.5%)	02 (40%)	02 (40%)	01 (20%)
13.	Rhus toxicodendron	01 (1.8%)	01 (100%)	00 (0%)	00 (0%)
14.	Sabadilla	03 (5.2%)	01 (33%)	02 (67%)	00 (0%)
15.	Sulphur	01 (1.8%)	00 (0%)	00 (0%)	01 (100%)
Total		59 (100%)	36 (61%)	15 (25.5%)	08 (13.5%)

The most frequent potency used in this observational study was 30CH potency (n=49; 83%). Some cases also required 200CH potency (n=10; 17%) according to the susceptibility of the patient & intensity of the symptoms, but 1M or higher potencies were not required in any of the cases.

Common Cold Questionnaire (CCQ) was used in this study to assess the treatment outcome in cases of Acute Nasopharyngitis. A total of 59 patients were assessed before and after treatment, using Common Cold Questionnaire (CCQ) scores. 36 patients (61.0%) showed improvement in CCQ score and relief in all complaints; 15 patients (25.5%) were at status quo, showing no change in CCQ score or difference less than 6 in CCQ score after treatment, with no specific relief in symptoms and 08 patients (13.5%) became worse, showing an increase in CCQ score along with worsening of symptoms.

The statistical test used to analyze the CCQ scores was Paired t-test. The analysis was done on IBM SPSS 25.0. So, Sample size (per protocol) is 59, for which degree of freedom (n-1) = 58 and level of significance is $\alpha = 0.05$.

Paired t-test:
$$t_{(cal)} = \frac{\bar{d}}{sd/\sqrt{n}} \sim t_{(n-1)}$$

$$\bar{d} = \frac{1}{n} \sum_{i=0}^n d_i \text{ and } s_d = \sqrt{\frac{1}{n-1} \sum_{i=0}^n (d_i - \bar{d})^2}$$

- df = n-1 = 59-1 = 58.
- n = Total number of patients i.e. 59.
- d = Mean of samples.

Table III: Mean & Standard deviation of the samples

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Score(before t/t)	12.93	59	2.100	0.273
	Score(after t/t)	5.66	59	5.467	0.712

Table IV: Paired t-test

Paired Samples Test									
		Paired Differences			95% Confidence Interval of the Difference				Sig. (2-tailed) (p)
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	
Pair 1	Score(before t/t) - Score(after t/t)	7.271	6.646	0.865	5.539	9.003	8.404	58	0.000

Paired t-test (Table IV) was conducted to assess the effectiveness of characteristic keynote prescription of homoeopathic medicines in cases of Acute Nasopharyngitis. The result (Table IV) showed that p value was < 0.05 & value of t (8.404) was greater than the tabulated value in t-table at df = 58 (2.002), which was statistically significant which justifies that characteristic keynote prescription of homoeopathic medicines is effective in cases of Acute Nasopharyngitis. Thus, keynote prescribing methodology can be useful in treating acute diseases & paediatric patients, but it will require a sound knowledge of our Materia Medica along with Organon of Medicine and an 'Unprejudiced' Observer.

There are also certain limitations of this study. This observational study was on an acute disease which is self-limiting, so in some cases which showed improvement after 5 to 6 days, it was difficult to analyse the true effect of homoeopathic remedies. It was also difficult to record exact symptoms in many cases as the affected age group of children was not able to narrate subjectively & we had to be dependent on the parents or attendants for case recording.

The study design was observational which is not considered as the standard research design as randomized control trials along with single or double blinding is considered as the 'gold standard' in the field of medical research. Since the sample size was also small in this observational study, so generalizing the result and conclusions of this study need to be done very cautiously.

The findings of this study warrant further evaluation using better study designs with large sample size and enhanced methodological rigor. Hence, further more extensive studies will be required with better statistical tools to establish the outcome results of this observational study.

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Conflicts of Interest

There are no conflicts of interest.

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