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Effect of homoeopathic medicines on daily burden of symptoms in children with recurrent upper respiratory tract infections

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Abstract

***Objective*—To investigate the intrinsic effects of individually prescribed homoeopathic medicines.**

***Design*—Randomised double blind placebo controlled study.**

***Setting*—Paediatric outpatient department of university hospital.**

***Patients*—175 children with frequently recurring upper respiratory tract infections. Of the 170 children evaluable, 86 were randomised to homoeopathic medicines (47 boys, 39 girls; median age at start 4·2 years; median number of episodes in past year 4) and 84 to placebo (43 boys, 41 girls; median age at start 3·6 years; median number of episodes in past year 4).**

***Main outcome measures*—Mean score for daily symptoms, number of antibiotic courses, and number of adenoidectomies and tonsillectomies over one year of follow up.**

***Results*—The mean daily symptom score was 2·61 in the placebo group and 2·21 in the treatment group (difference 0·41; 95% confidence interval −0·02 to 0·83). In both groups the use of antibiotics was greatly reduced compared with that in the year before entering the trial (from 73 to 33 in the treatment group and from 69 to 43 in the placebo group). The proportion of children in the treatment group having adenoidectomies was lower in the treatment group (16%, 8/50) than in the placebo group (21%, 9/42). The proportion having tonsillectomies was the same in both groups (5%).**

***Conclusion*—Individually prescribed homoeopathic medicines seem to add little to careful counselling of children with recurrent upper respiratory tract infection in reducing the daily burden of symptoms, use of antibiotics, and need for adenoidectomy and tonsillectomy.**

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Introduction

Some children get more upper respiratory tract infections such as acute otitis media, pharyngotonsillitis, and nasosinusitis than their peers.[1,2] Often no specific cause for increased susceptibility to upper respiratory tract infection can be found, and most children outgrow their susceptibility after the age of 6 years.

Homoeopathic doctors claim good results in treating children with recurrent upper respiratory tract infection.[3,4] The aim of homoeopathic treatment is to improve general health and reduce susceptibility. We conducted a randomised double blind placebo controlled clinical trial to study the effects of homoeopathic medicines on the frequency, duration, and severity of upper respiratory tract infections and the well being of children with recurrent upper respiratory tract infections. Individually chosen homoeopathic medicines were compared with appropriate placebos in two parallel groups. We report here the results for daily symptoms, numbers of antibiotic courses, and surgical interventions.

Patients and methods

Children aged between 1½ and 10 years were eligible for participation in the trial if they had had at least three upper respiratory tract infections in the past year or had had two such episodes and had otitis media with effusion at the time of the entry examination. We excluded children who had had adenoidectomy, tonsillectomy, or a "constitutional" homoeopathic treatment in the past six months; regular medical care for any other chronic condition including chronic non-specific lung disease; untreated dental caries; congenital malformation of the respiratory tract or the heart; mental handicap; neurological disorder; height outside the third centile; or a history of rheumatic fever, endocarditis, myocarditis, or nephritis. We also excluded children for whom no suitable homoeopathic constitutional medicine could be chosen at the entry examination because they did not have at least three symptoms relevant for the choice of a matching homoeopathic medicine, and children whose parents were not fluent enough in Dutch to answer the questionnaires.

Patients were recruited by their general practitioners and by articles in the popular press. The parents of 358 children responded, and we excluded 183. Reasons for exclusion were too few episodes of upper respiratory tract infection in the past year, refusal of informed consent, the presence of another chronic disease.

The entry examination comprised a detailed medical history, clinical examination by a homoeopathic doctor (ESMdLdk) and ear, nose, and throat specialist (LF), and some laboratory tests to exclude serious disease (erythrocyte sedimentation rate, haemoglobin concentration, packed cell volume, leucocytes, count, and IgA, IgM, and IgG titre).

We assigned children to the study groups using permuted blocks (size 4) stratified for age in (18-23 months, 2 to 5 years, and 6 to 9 years). This achieves balance for age and also for any variables which tend to vary over time or season.

TREATMENT

All parents were provided with written advice on adequate nutrition—that is, little sugar, wholemeal products, plenty of fruit and vegetables, no pork, and half a litre milk daily.

Homoeopathic medicines were chosen individually for each participating child. Several could be prescribed successively, follow up prescriptions were based on the clinical course. The child was given either active medicine or a placebo for the appropriate treatment for the whole study period. The homoeopathic treatment consisted of constitutional medicines for improving general health in the long run and acute medicines for treating acute upper respiratory tract infections. Constitutional medicines were selected according to general and mental characteristics, the child's history, and family history. If necessary a computer was used to match the symptoms with the most appropriate treatment. Several potencies were used, mainly the 6th, the 30th and the 200th decimal.

Children were not allowed to take any homoeopathic medicines other than those supplied by the trial doctor, but non-homoeopathic drugs were prescribed by the child's general practitioner or specialist, if needed. All drugs taken were carefully recorded.

The children were seen regularly by the homoeopathic doctor. The consultation scheme was flexible, and consultations took place whenever considered necessary usually every two months. The homoeopathic doctor could be contacted daily by telephone. The study was approved by our university hospital's medical ethics committee.

ASSESSMENT AND ANALYSIS OF DATA

The parents kept diaries, and their observations were collected once every two weeks through structured telephone interviews. The diaries contained information on lack of energy, fever, tummy ache, headache, nasal discharge, nasal obstruction, sore throat, earache, ear discharge, hearing problems, cough, drugs taken, consultations with doctors, absence from school, and illnesses in the family. We designed a daily symptom score to measure the burden of symptoms of upper respiratory tract infections. The score has four dimensions: symptoms of the nose, ear, and throat, and general symptoms. Since we were mainly interested in symptoms caused by upper respiratory tract infection, respiratory symptoms were given greater weight than general symptoms. The daily score could vary between 0 (no symptoms) and 56 (many symptoms). Respiratory symptoms could add to a maximum of 42, general symptoms to a maximum of 14. Antibiotic courses, adenoidectomies, and tonsillectomies were recorded and counted.

We calculated each child's daily symptom score for each day of follow up. The child's mean of daily symptom score was calculated for the year and last nine months of follow up. We also calculated group means. Student's t test was used to assess differences in means and χ^2 tests for differences in proportions. Two tailed P values and 95% confidence intervals are presented. A stepwise forward multiple linear regression model was used to estimate differences of means of the daily symptom scores adjusted for small differences in prognostic factors at baseline. The identity of the treatment groups was concealed until all the data analysis was complete.

TABLE I—*Mean daily symptom scores for year of follow up in children with recurrent upper respiratory tract infections*

Age group (years)	Placebo group: No of children	Placebo group: Mean score	Treatment group: No of children	Treatment group: Mean score	Differences in mean (95% confidence interval)	Ratio of means
1·5-<2	4	2·77	3	2·02	0·75 (-0·67 to 2·18)	0·73
2-5	71	2·69	73	2·31	0·38 (-0·09 to 0·85)	0·86
6-9	9	1·93	10	1·52	0·41 (-0·92 to 1·73)	0·79
All ages	84	2·61	86	2·21	0·41 (-0·02 to 0·83)	0·85

Results

A total of 175 children were eligible for study. The study ran from March 1987 to January 1992. Data were analysed for all 170 children who participated for more than 26 weeks, including three children (one in the treatment group, two in the placebo group) who stopped taking trial treatment but continued follow up. Five children (two in the treatment group, three in the placebo group) participated for less than 26 weeks. Three children stopped treatment after 26 weeks (two in treatment group, one in placebo group), and their available data were included in the analysis. The main reason for stopping treatment was no improvement in clinical course (two in the treatment group and three in the placebo group).

Eighty six children were randomised to active medicine and 84 to placebo. The median age of the children on entering the trial was 4·2 (range 1·5 to 9·8) years in the treatment group and 3·6 (1·7 to 7·9) years in the placebo group. The median age at first respiratory infection was 10·8 months in the treatment group and 1 year in the placebo group. The treatment group contained 47 boys and 39 girls, the placebo group 43 boys and 41 girls. Data on perinatal history were comparable in both groups.

The lifetime prevalence of acute otitis media was 88% (76/86) in the treatment group and 89% (75/84) in the placebo group. In all, 64% (55) of the treatment group and 52% (44) of the placebo group had ever had otitis media with effusion, and 42% (36) of the treatment group and 48% (40) of the placebo group had ever had tonsillitis. Symptoms had been mainly in only one of the ear, nose, and throat in 16% (14) of the treatment group and 12% (10) of the placebo group, 58% (50) of the treatment group and 52% (44) of the placebo group had symptoms in two of these regions, and 26% (22) of the treatment group and 36% (30) of the placebo group had symptoms in all three regions.

The mean numbers of antibiotic courses for upper respiratory tract infections in the year before entering the trial was two in both groups. Thirty one children in the treatment group (36%) and 38 (45%) in the placebo group had had an adenoidectomy once; five children (6%) and four (5%) children respectively had had two adenoidectomies. Tonsillectomy was done on 9% (8) children in the treatment group and 11% (9) in the placebo group. Grommets had been placed in 20% (17) of children of the treatment group and 14% (12) in the placebo group. Most children had done well in the hearing test at 9 months (Ewing test).

Family composition, family history of respiratory and atopic diseases, housing conditions (including smoking in the home), and school and daycare attendance were similar in both groups at entry to the trial.

Data were missing for a mean of 2·8 days in children

TABLE II—*Mean daily symptom scores in last nine months of follow up in children with recurrent upper respiratory tract infections*

Age group (years)	Placebo group: No of children	Placebo group: Mean score	Treatment group: No of children	Treatment group: Mean score	Differences in mean (95% confidence interval)	Ratio of means
1·5-<2	4	2·58	3	2·02	0·56 (−1·31 to 2·43)	0·78
2-5	71	2·56	73	2·20	0·36 (−0·11 to 0·85)	0·86
6-9	9	1·77	10	1·49	0·28 (−1·09 to 1·66)	0·84
All ages	84	2·48	86	2·11	0·37 (−0·06 to 0·81)	0·85

TABLE III—*Number (percentage) of children having antibiotic treatment for respiratory and other problems according to randomisation to placebo (n=84) or treatment (n=86) groups*

No of courses	For respiratory problems: Placebo group	For respiratory problems: Treatment group	For other problems: Placebo group	For other problems: Treatment group	Respiratory or other problems: Placebo group	Respiratory or other problems: Treatment group
0	42 (50)	56 (65)	78 (93)	80 (93)	41 (49)	53 (62)
1	27 (32)	17 (20)	3 (4)	5 (6)	24 (29)	19 (22)
2	9 (11)	9 (11)	2 (2)	1 (1)	9 (11)	8 (9)
3	3 (4)	0	1 (1)	0	7 (8)	2 (2)
4	2 (2)	3 (3)	0	0	1 (1)	2 (2)
5	1 (1)	1 (1)	0	0	2 (2)	2 (2)
Total	84	86	84	86	84	86

in the treatment group and 2·6 days in children in the placebo group. Sixty one children had missing data; 53 children missed fewer than eight days and four (two of each group) missed more than a month.

Individual mean daily symptom scores ranged from 0·23 to 6·18 in the treatment group and from 0·21 to 6·85 in the placebo group. The difference in the group mean score over the whole year was 0·41 (P=0·06), the score being lower in the treatment group (table I). The difference over the last nine months was 0·37 (P=0·09; table II). The difference in mean daily symptom scores over the whole year was 0·32 (95% confidence interval −0·09 to 0·73; P=0·07) after small differences in prognostic factors at baseline were adjusted for stepwise forward multiple regression analysis.

The mean percentage of days with symptom score of zero (indicating symptom free days) was 53% (192 days) in the treatment group and 49% (178 days) in the placebo group (difference 4%; 95% confidence interval −3·6% to 11%).

The total number of antibiotic courses was 59 in the treatment group and 77 in the placebo group (table III). Most were seven day courses of broad spectrum penicillins, but 10 (12%) children in the treatment group and 14 (17%) in the placebo group (difference 5%; −5% to 15%) had one or more longer courses (table IV). Fifty three (62%) children in the treatment group and 41 (49%) in the placebo group did not have any antibiotic course (difference 13%; −2% to 28%).

The number of children taking antibiotics during the trial fell compared with the number taking them in the year before the trial. The reduction was from 73 to 33 (40) in the treatment group and from 69 to 43 (26) in the placebo group. The difference between the two groups was not significant (P=0·38).

Adenoidectomy was performed in 16% (8/50) of children in the treatment group who had never had an adenoidectomy before and in 21% (9/42) of such children of the placebo group (5%; −11% to 21%). Tonsillectomy was done in 5% of eligible children in the treatment and placebo groups (4/78 and 4/75 respectively). Nine children in the treatment group (10%) and 10 in the placebo group (12%) had paracentesis, 16 (19%) and 15 (18%) respectively had grommets, and two (2%) and one (1%) respectively had sinus drainage.

TABLE IV—*Numbers of extended courses of antibiotics taken during follow up by 14 children in placebo group and 10 in treatment group. All other children had only seven day courses or no antibiotics*

Length of course (days)	Placebo group	Treatment group
10-12	11	7
13-16	4	3
17-22	2	2
Total	17	12

Discussion

This study met the current conventional standards of a clinical trial[5] and the requirements of proper homoeopathic practice for the prescription and evaluation of medicines. In homoeopathy treatment is tailored to each patient after assessing the patient's general state of health in the long term rather than targeting particular diseases or symptoms in the short term. Since a child may have upper respiratory tract infections in the nose and paranasal sinuses, middle ear cavity, and throat simultaneously or subsequently,[6] it was inappropriate to restrict the study to infections of only one of these regions. The homoeopathic medicines were prescribed by a trained, qualified, and experienced homoeopathic doctor, who asked for a second opinion if a child was not doing well. The length of follow up period (one year) was, from a homoeopathic point of view, acceptable.

Before the study was carried out, it was presented to a homoeopathic[7] and a general medical forum and relevant criticism was integrated in the protocol. The randomised double blind placebo controlled design was used because we wanted to study the intrinsic effects of the homoeopathic medicines,[8] not the effects of the treatment as a whole, including counselling and advice.

Individual mean daily symptom scores were calculated for the whole year of follow up and for the last nine months separately because homoeopathic medicines are believed to need time to work. Symptoms may get temporarily worse shortly after taking an appropriate homoeopathic medicine.

The small difference in the mean daily symptom scores in the treatment and placebo groups was not significant (P=0·06 or 0·07 after correction for baseline differences). The difference over the last nine months was slightly smaller than the difference over the whole year. Antibiotic use during the trial and in the year before participation was compared, although it was measured in different ways (inventorised diaries once every two weeks and once only history taking respectively). A considerable reduction in use of antibiotics occurred in both groups. The reduction may have been due to several factors including growth and development of the child, dietary changes, other changes in life style, reduction of stress and anxiety by open medical access, and change of expectations. The homoeopathic medicine may also have played a part in the treatment group.

In the treatment group slightly fewer adenoidectomies were performed and fewer courses of antibiotics prescribed. The homoeopathic treatment aimed at preventing other interventions by improving the child's health. Use of interventions such as antibiotics

Clinical implications

- Some children suffer more and longer episodes caused by upper respiratory tract infections than their peers
- Homoeopathic doctors claim success in the treatment of such children
- In this study the small difference in symptom score found in favour of the homoeopathic medicines was not significant
- Antibiotic use was reduced greatly in both groups, but slightly more in the treatment group
- Homoeopathic medicines produce no clinically relevant improvement in recurrent upper respiratory tract infection

gives some indication of the severity of infections and thus of the effectiveness of trial therapy, but the interventions may also have reduced daily symptom scores. The small differences between the groups are, however, consistently in favour of the treatment group, so that the difference in mean daily symptom score cannot have been brought about by the use of more antibiotics. The difference might have been slightly reduced by greater use of antibiotics in the placebo group. In conclusion, the observed differences between the groups were small but consistent. The clinical relevance, however, is questionable.

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Educational status, coronary heart disease, and coronary risk factor prevalence in a rural population of India

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Abstract

***Objective*—To define the association between educational level and prevalence of coronary heart disease and coronary risk factors in India.**

***Design*—Total community cross sectional survey with a doctor administered questionnaire, physical examination, and electrocardiography.**

***Setting*—A cluster of three villages in rural Rajasthan, western India.**

***Subjects*—3148 residents aged over 20 (1982 men, 1166 women) divided into various groups according to years of formal schooling.**

***Results*—Illiteracy and low educational levels were associated with less prestigious occupations (agricultural and farm labouring) and inferior housing. There was an inverse correlation of educational level with age (rank correlation: men -0·45, women -0·49). The prevalence of coronary heart disease (diagnosed by electrocardiography) was significantly higher among uneducated and less educated people and showed an inverse relation with education in both sexes. Among uneducated and less educated people there was a higher prevalence of the coronary risk factors smoking and hypertension. Educational level showed a significant inverse correlation with systolic and diastolic blood pressure. Logistic regression analysis with adjustment for age showed that educational level had an inverse relation with prevalence of electrocardiographically diagnosed coronary heart disease (odds ratio: men 0·82, women 0·53), hypertension (men 0·88, women 0·56), and smoking (men 0·73, women 0·65) but not with hypercholesterolaemia and obesity. The inverse relation of coronary heart disease with educational level abated after adjustment for smoking, physical activity, body mass index, and blood pressure (odds ratio: men 0·98, women 0·78).**

***Conclusion*—Uneducated and less educated people in rural India have a higher prevalence of coronary heart disease and of the coronary risk factors smoking and hypertension.**

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Introduction

In developed countries low social class is an important determinant of coronary heart disease incidence as well as of mortality.[1,2] Coronary risk factors also are more prevalent in lower social classes.[3,4] In developed countries educational level accurately reflects social class and may be a more important risk factor than social or economic class alone.[5,6] However, studies from developing countries have shown no such correlation. The few studies from rural and urban areas of India that have examined this question[7-10] suggest that coronary risk increases with social class and that coronary heart disease is more common among wealthier groups.[7] Socioeconomic strata and prevalence of coronary risk factors have not been studied adequately in other developing countries.[11]

To define the association between level of education and the prevalence of coronary heart disease and coronary risk factors we performed a cross sectional survey in a rural population of Rajasthan, India. Rural areas of Rajasthan have a high prevalence of illiteracy (45% of men, 70% of women)[12] and provide a useful model for assessing the influence of illiteracy and of different levels of education on various coronary risk factors and the prevalence of coronary heart disease.

Methods

A doctor administered questionnaire was prepared according to guidelines of the World Health Organisation,[13] and United States National Institutes of Health.[14] The questionnaire included social factors such as details of education, housing, and type of job. Subjects who had not received any formal education were placed in the uneducated group (group 1). Number of years of education was calculated from the highest class achieved in school or college. Educated subjects were subdivided in groups of five years: up to five years of education (group 2) corresponded to primary school level, up to 10 years (group 3) to secondary school level, and more than 10 years (group 4) to higher secondary or college level education. Size of income was ignored because accurate estimates of income are not generally available in India. A history of conventional risk factors such as smoking, lack of exercise, hypertension, diabetes, and chest pain (Rose questionnaire[13]) was sought.

The study was conducted in villages picked at random, away from major towns. A cluster of three villages in Parbatsar tehsil (county) of Nagaur district of central Rajasthan were identified and all residents aged 20 and over scheduled to be examined. Of the 2188 men and 1968 women aged over 20 whose names appeared on the voters' lists, 1982 (90·6%) men and