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Pharmacoeconomic comparison between homeopathic and antibiotic treatment strategies in recurrent acute rhinopharyngitis in children

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Objectives: A pharmacoeconomic study to compare, in terms of: medical effectiveness, quality of life and costs two treatment strategies ('homeopathic strategy' vs 'antibiotic strategy') used in routine medical practice by allopathic and homeopathic GPs in the treatment of recurrent acute rhinopharyngitis in 18-month to 4-year-old children.

Methods: Statistical analysis of data obtained from a population of 499 patients included in a previous 6-month prospective, pragmatic study. The patients were re-grouped according to type of drug prescribed. Medical effectiveness was assessed in terms of (i) episodes of acute rhinopharyngitis, (ii) complications, (iii) adverse effects. Quality of life was assessed using the Par-Ent-QoL scale. Direct medical costs (medical consultations, drug prescriptions, prescriptions for further tests) and indirect medical costs (sick-leave) were evaluated from three viewpoints (society, patient, Social Security) using public prices and French Social Security tariffs.

Results: The 'homeopathic strategy' yielded significantly better results than the 'antibiotic strategy' in terms of medical effectiveness (number of episodes of rhinopharyngitis: 2.71 vs 3.97, $P < 0.001$; number of complications: 1.25 vs 1.95, $P < 0.001$), and quality of life (global score: 21.38 vs 30.43, $P < 0.001$), with lower direct medical costs covered by Social Security (88€ vs 99€, $P < 0.05$) and significantly less sick-leave (9.5% of parents vs 31.6% of parents, $P < 0.001$).

Conclusions: Homeopathy may be a cost-effective alternative to antibiotics in the treatment of recurrent infantile rhinopharyngitis. *Homeopathy* (2005) 94, 3–9.

Keywords: recurrent acute rhinopharyngitis; homeopathy; antibiotics; cost; effectiveness; quality of life

Introduction

Acute infantile rhinopharyngitis is a common clinical problem: it is most frequent in children between 6 months and 3 years of age, its prevalence diminishes after 5 years of age. In France, more than 5 million cases are recorded each year in children under 7 years.¹ Antibiotics and homeopathy are amongst the most commonly prescribed treatments for this disease.²

Inappropriate and excessive use of antibiotics has led to bacterial resistance, a serious economic and ecological public health problem.^{3–9} A previous study on the treatment of the disease by homeopathic and allopathic GPs, suggested that homeopathy, which has no known adverse effects, could constitute a cost-effective alternative to antibiotics.² This hypothesis may only be confirmed objectively by a pharmacoeconomic study. We therefore compared in terms of medical effectiveness, quality of life and costs, the following two drug strategies:

- 'Homeopathic strategy' (Strategy H): treatment of recurrent acute infantile rhinopharyngitis

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with homeopathy (not combined with antibiotics),

- 'Antibiotic strategy' (Strategy A): treatment of recurrent acute infantile rhinopharyngitis with antibiotics (not combined with homeopathy).

In both strategies, other drugs (such as mucus fluidifiers, trace elements, corticosteroids, antipyretics) could have been prescribed.

Methods

Study design

Our study is non-randomised and is a *post hoc* analysis. We conducted a statistical analysis of patient data from a previous medicoeconomic prospective and pragmatic study comparing medical effectiveness, quality of life and costs of the treatment of recurrent acute infantile rhinopharyngitis by allopathic and homeopathic GPs.² This previous study conducted in France in 2000/2001, included 499 children. Two hundred and thirty-one were treated by 62 non-homeopathic GPs and 268 by 73 homeopathic GPs. The effectiveness (assessed as complications/patient, total number of adverse events) and quality of life (assessed by the Par-Ent-Qol⁽¹⁾ scale) were better in the homeopathic GPs group than in the non-homeopathic GPs group. No significant difference was found between the two groups for the total costs to social security. Homeopathic GPs prescribed preventive treatment for 82.2% of their patients and antibacterials for 20.9% of them, while non-homeopathic GPs initiated preventive treatment in 43.3% of their patients and prescribed antibacterials for 89.6% of them. In the database homeopathy and antibiotics represented:

- respectively 74% and 3% of prescriptions of homeopathic GPs,
- respectively 11% and 26% of prescriptions of allopathic GPs.²

For our study, we used the database of this previous study, reorganising the data according to type of drug prescribed, irrespective of the type of GP consulted. We thus defined the following two patient-groups for comparison:

- group H: patients having received at least one homeopathic drug and no antibiotic,
- group A: patients having received at least one antibiotic and no homeopathic drug.

In both groups patients could have been prescribed other drugs such as mucus fluidifiers, trace elements, corticosteroids, antipyretics. Homeopathic drugs were chosen by GPs according to clinical symptoms of patients. One or several homeopathic drugs could have been prescribed for the same patient.

Statistical analysis

The data of the two patient-groups was compared by statistical analysis after checking for comparability. The statistical tests used depended on the type of variable:

- qualitative variables: χ^2 test,
- quantitative variables: Student's, Mann-Whitney, and Kolmogorov-Smirnov tests.

The alpha error was fixed at 5%.

Sample groups and duration of follow-up

The samples were established according to type of drug prescribed by homeopathic and allopathic GPs:

- group H: patients who received at least one homeopathic drug and no antibiotic,
- group A: patients who received at least one antibiotic and no homeopathic drug.

The two samples of GPs (homeopathic and allopathic) randomly selected from two sources:

- Allopathic GPs were selected from Pharbase®, a database of IMS Health listing medical and paramedical professionals;
- Homeopathic GPs were selected from the France Telecom phone directory database with 'homeopathic orientation': GPs who have received approval by the *Conseil National de l'Ordre des Médecins* (French national medical authority) to be listed under this heading, implying that they have been specifically trained in homeopathy.

The study lasted 6 months (from September to April), in order to follow the management during winter, when the disease is most common. The duration of follow-up was decided by homeopathic and allopathic clinical experts. We sought to investigate a situation as close as possible to the everyday realities of general medical practice. During the monitoring period (initial, intermediate and final consultations), data were collected in case reports completed by the GPs. Quality of life was assessed by parents at the end of the monitoring period.

Patients

Database

The database included 499 patients. The 499 patients were recruited in 2000 and monitored for 6 months (between September and April) by 135 GPs (62 allopathic and 73 homeopathic).

Inclusion criteria:

- children between 18 months and 4 years of age,
- children who suffered at least 5 bouts of acute rhinopharyngitis in 1999, and who consulted a GP in

2000 either for preventive treatment or for treatment of a current episode.

Diagnostic criteria for acute rhinopharyngitis:

- rhinorrhœa and/or cough,
- temperature $\geq 38^{\circ}\text{C}$ within 24 h of inclusion.

Exclusion criteria:

- parental illiteracy,
- severe immunodepression,
- deficient inclusion criteria.

Patient groups

Two types of patient were selected from the database:

- patients who had received at least one homeopathic drug and no antibiotic (group H),
- patients who had received at least one antibiotic and no homeopathic drug (group A).

Both types of patient could have been prescribed other drugs.

Assessment criteria

The same three assessment criteria, medical effectiveness, quality of life, and costs, as in the previously published study² were used.

Medical effectiveness

Medical effectiveness was assessed in terms of:

- (i) number of episodes of acute rhinopharyngitis following inclusion,
- (ii) number of complications,
- (iii) number of adverse effects.

Quality of life

Quality of life was assessed by parents at the end of the monitoring period using the Par-Ent-Qol¹ scale which has been validated for this type of disease.¹⁰ The scale includes three subscales: 'Emotion Score', a 'Daily Disturbance Score', and a 'Global Score'. The scales range from 0 to 100. A score of 0 indicates no effect on the quality of family life; a score of 100 represents maximum effect on the quality of family life.

Costs

All prescriptions made by the GPs were recorded in forms which were completed at the time of the consultation. For the purposes of the study, costs were divided into:

- direct medical costs (medical consultations, drug prescriptions, requests for further tests),
- indirect medical costs (number and duration of sick leave, not economically evaluated).

Costs were calculated according to (i) public prices (2000) and (ii) the Social Security nomenclature for medical acts or services (2000).

Medical consultations were coded as initial, intermediate and final consultations. Drug prescriptions included all medicines prescribed to treat acute rhinopharyngitis such as antibiotics, homeopathic drugs, mucus fluidifiers, trace elements, corticosteroids, antipyretics, etc.

Costs were assessed in terms of:

- overall cost,
- Social Security cost,
- residual cost to patient and/or mutual benefit company and/or covered by complementary insurance.

Results

Patients

Four hundred and thirty-one out of the 499 database patients met both the inclusion and selection criteria. Sixty-eight files were excluded for the following reasons: 55 patients were treated with homeopathic drugs and antibiotics, 12 patients were treated neither by antibiotic nor by homeopathic drug and data from 1 patient missing.

Two hundred and forty-one patients (55.9%) were included in group H and 190 patients (44.1%) in group A. Two hundred and twenty-two patients (92.1%) from group H had consulted a homeopathic GP, 19 (7.9%) had consulted an allopathic GP. One hundred and seventy-seven patients (93.2%) from group A had consulted an allopathic GP and 13 (6.8%) had consulted a homeopathic GP.

The two patient-groups were checked for comparability, results are summarised in Table 1:

- The two groups of patients were homogeneous in terms of socio-demographic criteria: sex, age, housing, employment, type of Social Security coverage and mutual benefit. The differences between the groups related to culture and lifestyle. The statistically significant differences were: 'usual form of childcare' ('child kept at home': $H = 39.9\%$ of patients *vs* $A = 53.2\%$, $P = 0.02$) and 'passive smoking' ($H = 16.7\%$ of patients *vs* $A = 33.5\%$, $P < 0.001$).
- The two groups of patients were somewhat statistically heterogeneous in terms of clinical criteria. Group H patients were prescribed significantly more preventive treatment than group A ($H = 86.5\%$ of patients *vs* $A = 37.6\%$, $P < 0.001$). Patients of group H had significantly less treatment of a current episode than patients of group A ($H = 55.8\%$ of patients *vs* $A = 86.2\%$, $P < 0.001$), and fewer complications ($H = 21.9\%$ of patients *vs* $A = 31.4\%$, $P = 0.03$) and fewer of these children were ill at the time of

Table 1 Comparability of patient-groups

Characteristics	Statistical results	Comments
<i>Socio-demographic data concerning child</i>		
Age	Homogeneous (Student's, Mann-Whitney, Kolmogorov-Smirnov tests, $P > 0.05$)	A = 2.97 years vs H = 2.84 years
Sex	Homogeneous (χ^2 test, $P = 0.58$)	Male: A = 54.2% vs H = 56.8%
Usual form of child-minding	Heterogeneous (χ^2 test, $P = 0.02$)	For criterion 'child kept at home': A = 53.2% vs H = 39.9%
Passive smoking	Heterogeneous (χ^2 test, $P < 0.001$)	A = 33.5% vs H = 16.7%
<i>Socio-demographic data concerning person in charge of child</i>		
Housing	Homogeneous (χ^2 test, $P = 0.40$)	Urban: A = 56.4% vs H = 60.4%
Employment	Homogeneous (χ^2 test, $P = 0.05$)	A = 93.9% vs H = 98.2%
Type of employment	Heterogeneous (χ^2 test, $P < 0.001$)	For criterion 'blue/white-collar employment'
Type of Social Security coverage	Homogeneous (χ^2 test, $P = 0.33$)	
Mutual benefit	Homogeneous (χ^2 test, $P = 0.32$)	A = 96.3% vs H = 97.9%
<i>Clinical state of patients at inclusion</i>		
Preventive treatment	Heterogeneous (χ^2 test, $P < 0.001$)	A = 37.6% vs H = 86.5%
Treatment of a current episode	Heterogeneous (χ^2 test, $P < 0.001$)	A = 86.2% vs H = 55.8%
Complication	Heterogeneous (χ^2 test, $P = 0.03$)	A = 31.4% vs H = 21.9%
Type of complication	Not measured	Insufficient number of patients
Child ill	Heterogeneous (χ^2 test, $P < 0.001$)	A = 93.2% vs H = 61.0%

Table 2 Medical effectiveness results

Medical effectiveness Criteria	Results		Statistical Results
	Strategy H (241 patients)	Strategy A (190 patients)	
<i>Bouts of ARP^a per patient</i>			
<i>Including initial consultation</i>			
Average number (95% CI)	2.71 (2.46-2.96)	3.97 (3.65-4.30)	$H > A$ ($P < 0.001$)
Standard deviation	1.97	2.29	
<i>Excluding initial consultation</i>			
Average number (95% CI)	2.17 (1.94-2.41)	3.12 (2.80-3.44)	$H > A$ ($P < 0.001$)
Standard deviation	1.84	2.25	
<i>Complications of ARP^a per patient</i>			
<i>Including initial consultation</i>			
Average number (95% CI)	1.25 (1.05-1.45)	1.95 (1.69-2.20)	$H > A$ ($P < 0.001$)
Standard deviation	1.58	1.78	
<i>Excluding initial consultation</i>			
Average number (95% CI)	1.06 (0.90-1.22)	1.81 (1.57-2.04)	$H > A$ ($P < 0.001$)
Standard deviation	1.27	1.63	
Side-effects	4.6%	4.2%	$H = A$ (χ^2 test, $P = 0.86$)
<i>Intermediate consultations per patient</i>			
Average number (95% CI)	1.80 (1.61-2.00)	2.81 (2.54-3.08)	$H > A$ ($P < 0.001$)
Standard deviation	1.51	1.91	

Note: ^aAcute rhinopharyngitis; ^bStudent's, Mann-Whitney, Kolmogorov-Smirnov tests; $H > A$: Strategy H is significantly superior to Strategy A in terms of medical effectiveness; $H = A$: Strategy H and Strategy A are statistically equivalent in terms of medical effectiveness.

study entry ($H = 61.0\%$ of patients vs $A = 93.2\%$, $P < 0.001$).

Our statistical expert concluded that overall the two groups were comparable. We were thus able to compare them.

Medical effectiveness

Medical effectiveness results are summarised in Table 2. Patients in group H had significantly lower bouts of acute rhinopharyngitis (2.71 per patient vs

3.97, $P < 0.001$) and fewer complications (1.25 per patient vs 1.95, $P < 0.001$) than patients of Strategy A. There was no significant difference between the two groups in terms of side effects (4.6% of patients vs 4.2%, $P = 0.86$). There were fewer intermediate consultations per patient in Strategy H during the monitoring period (1.80 vs 2.81, $P < 0.001$). Thus, the 'homeopathic drug strategy' (Strategy H) was globally more medically effective than the 'antibiotic drug strategy' (Strategy A) for the treatment of recurrent acute infantile rhinopharyngitis.

Quality of life

Quality of life results are summarised in Table 3. The three subscales of the Par-Ent-Qol[®] scale were significantly in favour of the patients of group H:

- 'Emotion score': 24.81 vs 33.72 ($P < 0.001$).
- 'Daily disturbance score': 16.79 vs 26.03 ($P < 0.001$).
- 'Global score': 21.38 vs 30.43 ($P < 0.001$).

The quality of life was therefore better with the 'homeopathic drug strategy'.

Costs

Direct medical costs

Results are summarised in Table 4. The 'homeopathic drug strategy' incurred the Social Security significantly lower direct medical costs than the 'antibiotic drug strategy' (88€ per patient vs 99€, $P < 0.05$). However, there was no significant difference between the two groups in terms of costs to the Social

Security for medicines (41€ per patient vs 37€, $P > 0.05$) or tests (22€ per patient vs 22€, $P > 0.05$). Strategy H incurred the Social Security significantly lower GP visit costs than Strategy A (47€ per patient vs 59€, $P < 0.001$). But Strategy A incurred the patient lower direct medical costs than Strategy H (73€ per patient vs 86€, $P < 0.05$). Patients taking homeopathy therefore personally cover a greater part of their health expenses.

Indirect medical costs

Sick-leave was assessed by the number of parents having at least one period of leave to care for a sick child during follow-up. Significantly fewer periods of leave to care for a child occurred in the 'homeopathic strategy' (Strategy H) compared with the 'antibiotic strategy' (Strategy A): 9.5% of parents of group H vs 31.6% of parents of group A (χ^2 test, $P < 0.001$). The duration of the leave was similar with both strategies:

Table 3 Quality of life results

Quality of life Par-Ent-Qol scale	Results		Statistical Results
	Strategy H (241 patients)	Strategy A (190 patients)	
Emotion Score			
Mean score (95% CI, SD)	24.81(22.43–27.19, 18.67)	33.72(30.63–36.82, 20.79)	$H > A$ ($P < 0.001^{**}$)
Daily Disturbance Score			
Mean score (95% CI, SD)	16.79(14.65–18.94, 16.82)	26.03(23.31–28.76, 18.30)	$H > A$ ($P < 0.001^{**}$)
Global Score			
Mean score (95% CI, SD)	21.38(19.23–23.52, 16.81)	30.43(27.71–33.15, 18.29)	$H > A$ ($P < 0.001^{**}$)

Note: **Student's, Mann-Whitney, Kolmogorov-Smirnov tests; SD = standard deviation; $H > A$: Strategy H is significantly superior to Strategy A in terms of quality of life.

Table 4 Costs results

Direct costs	Results		Statistical Results
	Strategy H (241 patients)	Strategy A (190 patients)	
Cost per patient (covers 6-month monitoring period)			
Drugs			
Average overall cost (95% CI, SD)	78€ (65–91€, 100€)	70€ (64–76€, 42€)	$H = A$ ($P > 0.05^{***}$)
Average Social Security cost (95% CI, SD)	41€ (33–48€, 60€)	37€ (34–41€, 25€)	$H = A$ ($P > 0.05^{***}$)
Average cost to patient (95% CI, SD)	37€ (32–43€, 44€)	33€ (30–35€, 18€)	$H = A$ ($P > 0.05^{***}$)
Medical consultations			
Average overall cost (95% CI, SD)	95€ (90–100€, 39€)	97€ (92–103€, 40€)	$H = A$ ($P > 0.05^{***}$)
Average Social Security cost (95% CI, SD)	47€ (44–49€, 18€)	59€ (56–62€, 23€)	$H < A$ ($P < 0.001^{**}$)
Average cost to patient (95% CI, SD)	48€ (46–36€, 20€)	38€ (36–41€, 18€)	$H > A$ ($P < 0.001^{**}$)
Further tests			
Average overall cost (95% CI, SD)	34€ (24–44€, 13€)	34€ (23–46€, 28€)	$H = A$ ($P > 0.05^{***}$)
Average Social Security cost (95% CI, SD)	22€ (15–29€, 9€)	22€ (15–30€, 18€)	$H = A$ ($P > 0.05^{***}$)
Average cost to patient (95% CI, SD)	12€ (9–15€, 4€)	12€ (8–16€, 10€)	$H = A$ ($P > 0.05^{***}$)
Total			
Average overall cost (95% CI, SD)	174€ (159–189€, 118€)	172€ (161–183€, 77€)	$H = A$ ($P > 0.05^{***}$)
Average Social Security cost (95% CI, SD)	88€ (80–90€, 68€)	99€ (93–106€, 45€)	$H < A$ ($P < 0.05^{***}$)
Average cost to patient (95% CI, SD)	86€ (79–93€, 54€)	73€ (68–78€, 33€)	$H > A$ ($P < 0.05^{***}$)

Note: SD: standard deviation; **Student's, Mann-Whitney, Kolmogorov-Smirnov tests; ***Student's, Mann-Whitney tests; ****Mann-Whitney, Kolmogorov-Smirnov tests; $H > A$: Strategy H is significantly more expensive than Strategy A; $H < A$: Strategy H is significantly less expensive than Strategy A; $H = A$: Strategy H and Strategy A are statistically equivalent in terms of costs.

3.39 days with Strategy H vs 4.33 days with Strategy A ($P > 0.05$).

Discussion

The aim of this study was to compare, in terms of medical effectiveness, quality of life and costs, two treatment strategies ('homeopathic strategy' vs 'antibiotic strategy') applied by GPs in the treatment of recurrent acute infantile rhinopharyngitis. The two strategies were compared by statistical analysis of data obtained from the database of a patient population included in a previous study on this disease, the patients had been re-grouped according to type of drug prescribed. We included patients aged between 18 months and 4 years in the study, as this is the age-group at which incidence and prevalence of the disease are maximal. The study period (September-April) corresponds to the period during which the disease is most common. The medical effectiveness criteria selected for this study were validated by homeopathic and allopathic clinical experts. Quality of life was only assessed for current episodes of rhinopharyngitis, as the Par-Ent-Qol scale is not validated for retrospective assessments.

The major limitation of this study is the fact that both patient groups could have received other drugs (mucus fluidifiers, trace elements, corticosteroids, antipyretics, etc.). This could influence results of study in terms of effectiveness and costs. However, as the study is a true reflection of urban GP practice, these other drugs were prescribed indiscriminately.

Another important limitation of this study concerns the comparability of the two samples of patients although they were generally similar, they differed with respect to passive smoking and childcare. The children followed by GPs of group A were more exposed to passive smoking, which is important as this is a factor that increases the risk of recurrent acute rhinopharyngitis.¹¹ This non-homogeneity may have skewed the medical effectiveness results in favour of the patients of group H. Childcare arrangements are also important because children who are kept with other children recover less quickly.¹² Patients of group H were kept less at home than patients of group A, so this may have skewed the medical effectiveness results in favour of group A.

This study is a *post hoc* analysis. It adds value but it is limited because it was not planned at the beginning of the study. It was not randomised. The results could have been influenced by bias due to confounding factors differently distributed in the two groups. The results concerning adverse events must be interpreted with caution because it is difficult to establish the link between the treatment and adverse event with certainty. Furthermore, very few adverse events were reported in both groups. In our study physicians of group H were more likely than those of group A to

prescribe preventive treatment for recurrent acute rhinopharyngitis. This could explain why the children of group H suffered from fewer episodes. It would be interesting to carry out a double-blind randomised clinical study to investigate whether homeopathic medicines prevent recurrent episodes of acute rhinopharyngitis in children.

The total direct cost to the Social Security was lower in Strategy H. This could be explained by less intermediate consultations per patient in Strategy H during the monitoring period. Results were not representative for other countries because medical practice and health insurance systems differ between countries.

Ours is the only pragmatic study comparing homeopathy and antibiotics in the treatment of acute rhinopharyngitis published to date. As a result, we were unable to compare results with those of another study. It would be interesting to confirm these results with randomised clinical trials.

Conclusion

The 'homeopathic strategy' (Strategy H) appeared to be more medically effective and to be associated with a better quality of family life in the treatment of recurrent acute infantile rhinopharyngitis than the 'antibiotic strategy' (Strategy A), incurring the Social Security significantly lower direct medical costs and producing fewer sick-leaves. Homeopathy (prescribed chiefly by homeopathic GPs) could thus constitute a cost-effective alternative to antibiotics, providing an economical and ecological solution to public health problems caused by antibiotics (over-consumption and bacterial resistance respectively). Further research is required to confirm these first results.

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