Homeopathy (2012) 101, 224–230

http://dx.doi.org/10.1016/j.homp.2012.08.006, available online at http://www.sciencedirect.com

ORIGINAL PAPER

Individualized homeopathy in a group of Egyptian asthmatic children

Heba Farid Shafei[1,*], Soha Mahmoud AbdelDayem[2] and Nagwa Hassan Mohamed[1]

[1]*Complementary and Alternative Medicine Department, Medical Research Division, National Research Center, Cairo, Egypt*
[2]*Pediatrics Department, Medical Research Division, National Research Center, Cairo, Egypt*

Objectives: **To evaluate homeopathy as an adjunctive treatment for bronchial asthma in children.**
Methods: **In a prospective observational longitudinal study the effects of individualised homeopathic medicines were assessed in 30 children with asthma as an adjunct to conventional treatment. The main outcome measures were frequency of attacks, use of medication, night awakening and spirometry at baseline and at follow-up till 6 months.**
Results: **There were clinically relevant and statistically significant changes in those measuring severity, indicating relative improvements after 3 months and absolute improvements after 6 months of treatment by homeopathic medicines.**
Conclusions: **This study provides evidence that homeopathic medicines, as prescribed by experienced homeopathic practitioners, improve severity of asthma in children. Controlled studies should be conducted.** *Homeopathy* (2012) **101**, 224–230.

Keywords: Homeopathy; Childhood bronchial asthma; Homeopathic medicines; Spirometry; Simillimum; Observational study

Introduction

In many countries the prevalence of asthma is increasing, particularly in the 2nd decade of life when the disease affects 10–15% of the population.[1] Asthma is estimated to affect 7.7% of Egyptian school children.[2] World Health Organization (WHO) estimates that 235 million people globally suffer from asthma, it is a public health problem not just for high-income countries; it occurs in all countries regardless of the level of development.[3] It creates substantial burden to individuals and families and often restricts individuals' activities for a lifetime.

Current clinical practice guidelines from the National Heart, Lung, and Blood Institute (NHLBI)[4] and the Global Initiative for Asthma (GINA)[5] recommend the use of anti-inflammatory controller therapy for the long-term treatment of persistent asthma. Inhaled corticosteroids (ICS) are recommended and are used widely as first-line controller agents.[6]

Szefler and Martin[7] and Szefler[8] reviewed key studies conducted in the NHLBI Asthma Clinical Research Network (ACRN) and the Childhood Asthma Research and Education (CARE) Network. These two NIH asthma networks identified variable response to several long-term controller therapies, especially ICS and leukotriene receptor antagonists (LTRA). They concluded that these medications are sufficient for some but not all patients and that many children and adolescents may not achieve good asthma control despite consistent use of ICS. In Egypt, a study done in 2010 found that ICS at doses of >400 μg/day carry a significant risk of retarding height gain of asthmatic children while their continuous use for >1 year carries significant risks of short stature, weight gain and delayed puberty.[9]

Kurt et al noted the high prevalence of the use of CAM in allergic patients, and the tendency to discontinue drug therapy during this approach, hence the need to offer a scientific background to these practices.[10] Homeopathy is one of the most commonly used forms of CAM therapy.[11] The national regulatory framework and the place of homeopathy within the health care system differ from country to country, but the use of homeopathic medicines, mostly as non-prescription medicines, is growing in many parts of the world. For example, in the United States, adults spent 2.9

*Correspondence: HF Shafei, Complementary and Alternative Medicine Department, Medical Research Division, National Research Center, El-Bohouth Str, Dokki, POB 2311, Cairo, Egypt.
E-mail: hebashafei@yahoo.com
Received 16 October 2011; revised 17 May 2012; accepted 6 August 2012

billion US dollars on homeopathic products in 2007. In 2008, spending in France was more than US$408 million; Germany US$346m and in the UK more than US$62m.[12]

A thorough evaluation of homeopathic treatment for asthma is needed because several uncontrolled studies (without placebo control) have reported that such treatments are efficacious.[13–17] Several organisations have called for further research.[18–22] Reviews of placebo-controlled homeopathic clinical trials in general concluded that the effects of treatment cannot be attributed entirely to a placebo response but that there was insufficient evidence to support the use of homeopathic treatment for any single disease.[23,24]

We have undertook this study to determine whether homeopathic medicines, prescribed according to the principles of individualised classical homeopathy and given in addition to conventional medicine, are beneficial in the treatment of children with asthma.

Methods

A longitudinal observational study was conducted on all eligible asthmatic children (aged 7–15 years) attending the Homeopathic Clinic at the National Research Center, Cairo, Egypt from November 2008 until March 2010. Patients were referred by specialist physicians who had generally already made a clinical diagnosis according to the GINA classification.[5] The protocol of the study was approved by the Medical Research Ethical committee of the National Research Center.

All asthmatic children ($n = 42$) receiving β-agonist and/or corticosteroid inhalers regularly within the last year without apparent changes in asthma severity were included in the study. Children who had previously consulted a homeopath for any condition and received a homeopathic prescription were excluded, as were children who were unable to complete the necessary follow-up period or were suffering from systemic disease or congenital anomalies. We never advised stopping conventional treatments at the beginning of the study. We made clear to the patients that there is no incompatibility between conventional and homeopathic treatments.

Demographics and baseline severity

After obtaining written informed consent, demographic data and medical data were recorded. Severity of asthma was assessed according to: frequency of asthma attacks, night awakening, use of inhalers and oral corticosteroids requirement during the previous month. Diagnosis of asthma was made according to the guidelines of the Expert Panel Report 3 (EPR-3) of the National Institutes of Health and GINA.[4,5]

Physical examination was done to reveal findings that increase the probability of asthma, but the absence of these findings did not rule out asthma, because the disease is variable and signs may be absent between episodes. The examination focused on: upper respiratory tract (increased nasal secretion etc); chest (wheezing during normal breathing, hyperexpansion of the thorax, use of accessory muscles, appearance of hunched shoulders, chest deformity); and skin (atopic dermatitis, eczema).

Anthropometric measurements were done at entry and at the end of study. Height was measured twice at the same time of day and rounded to the nearest millimeter by the same observer, using a Harpenden Stadiometer. Patients' weight in kilograms was recorded using electronic balances. Anthropometric assessment was done at the entry, after 3 and 6 months. Quality of life was assessed using the Juniper Quality of Life Questionnaire for asthmatic children and their parents.[25] These results will be presented elsewhere.

Outcome measures

The main outcomes measures were clinical and spirometric measures, which constitute the main components for assessment of asthma severity according to the Global Strategy for Asthma Management and Prevention Classification[4] and GINA.[5] The clinical outcomes were: frequency of asthma symptoms (cough, shortness of breath, wheezes…), frequency of night awakening, frequency of usage of inhalers and frequency of exacerbations needing oral corticosteroids.

Respiratory function was assessed in the Pediatric Department by a chest specialist (2nd author). Respiratory functions tests were done in the morning between 09.00 and 12.00 for all included patients at the beginning of the study, at 3 months and at 6 months after starting homeopathic treatment. It comprised the following: Vital Capacity (VC), Forced vital capacity (FVC), Forced expiratory volume in the first second (FEV1), FEV1/FVC, Forced mid expiratory flow (FEF25–75%) and Peak expiratory flow (PEF). Results of spirometry were expressed as a percentage of predicted value adjusted for gender, age and height, according to Societas Europea Physiologic Clinicea Respiratoniae (ESPCR) guidelines.[26] The FVC, FEV1, FEF25–75% were considered abnormal if they were less than 80% of the normal predicted value. The FEV1/FVC ratio was considered abnormal if less than 75%.

Homeopathic prescriptions

Individualised homeopathy was provided by two trained classical homeopaths. Patients attended up to six homeopathic consultations over the course of 6 months, plus extra telephone consultations as necessary, according to normal practice. Repertorization was done twice, one manually (using Murphy's Homeopathic Medical Repertory) and Radar Homeopathic Software to ensure a uniform homeopathic management. Children were encouraged not to alter their conventional medication without advice from their asthma doctor. There was no maximum number of prescriptions allowed for each subject. To ensure reasonable uniformity of practice, the homeopaths held case conferences weekly. The homeopaths reported that their approaches were substantially the same and that any differences would be unlikely to affect the outcome.

Medicines were supplied by Helios homeopathic pharmacy (Tunbridge Wells, UK) in pellets. They were dispensed to mothers or care givers in solution form,

prepared by the homeopath themselves at the department. Mothers were informed about handling of bottles and dosage and also were instructed to report any reactions after starting treatment.

Statistical methods

Patient data (demographic data); clinical diagnoses according to EPR-3 and GINA; medicine prescribed; potency and dosage; prescription strategy, identification of the case as (intermittent or persistent) were collected on paper. Each patient was assigned a numerical identification code for the anonymous treatment of data. For purpose of analysis, severity was scored from 1 to14: intermittent (1−4); mild persistent (5−8), moderate persistent (9−12) and severe persistent asthma (13−14) depending on: frequency of episodes, frequency of night awakening, inhaler usage/day/week or/month and the need for oral corticosteroids usage per year during exacerbations. Statistical analyses were conducted using Statistical Package for Social Science (SPSS) program version 15 (Chicago, Illinois, USA). Data was summarized as number and percentage. The Wilcoxon test (for paired samples) was used for qualitative variables and paired *t* test was used for quantitative data since this data was normally distributed.

Results

Demographics

From 19 Nov. 2008 until 1st March 2010, 42 eligible patients attended the Homeopathic Clinic of the National Research Center, for a total of 128 visits. To assess the results of treatment, we analyzed the data of patients returning for at least one follow-up visit after the initial consultation (30 patients = 71.4%) with follow-ups up to 6 months (from one to 10 follow-up consultations). More than 50% of children attended five or more consultations.

Twelve patients (28.5%) failed to attend follow-up appointments. Parents of the 12 patients (three males and nine females) dropped after the first visit were contacted by telephone. The parents of the three males reported disappearance of symptoms, while parents of the nine females reported two reasons for dissatisfaction: problems of communication with the staff or to higher expectations than the results explained to them. The flow of patients through the study is shown in Figure 1.

Table 1 shows the demographic characteristics of the 30 included patients. The sample consisted of 21 male patients and nine female patients. Their age ranged from 7 to 15 years, with a mean weight and height 34.8 kg (±14.8) and 133.1 cm (±13.1). Most of children had one or more comorbid allergic manifestations: three children had eczema (10%), 10 rhinitis or sinusitis (33.3%) and nine conjunctivitis (30%). The duration of follow-up was 3−6 months for 56.6% of children (*N* = 17).

Treatments

The most common single polychrest medicines (*n* = 17) used were: *Arsenicum album*, *Baryta carbonica*, *Calcarea carbonica*, *Calcarea phosphorica*, *Cuprum metallicum*, *Hyoscyamus niger*, *Lachesis mutus*, *Lycopodium clavatum*, *Mercurius solubilus*, *Natrum muriaticum*, *Natrum sulphuricum*, *Phosphorus*, *Pulsatilla pratensis*, *Silicea terra*, *Sulphur*, *Thuja occidentalis*, *and Tuberculinum bovinum*, all

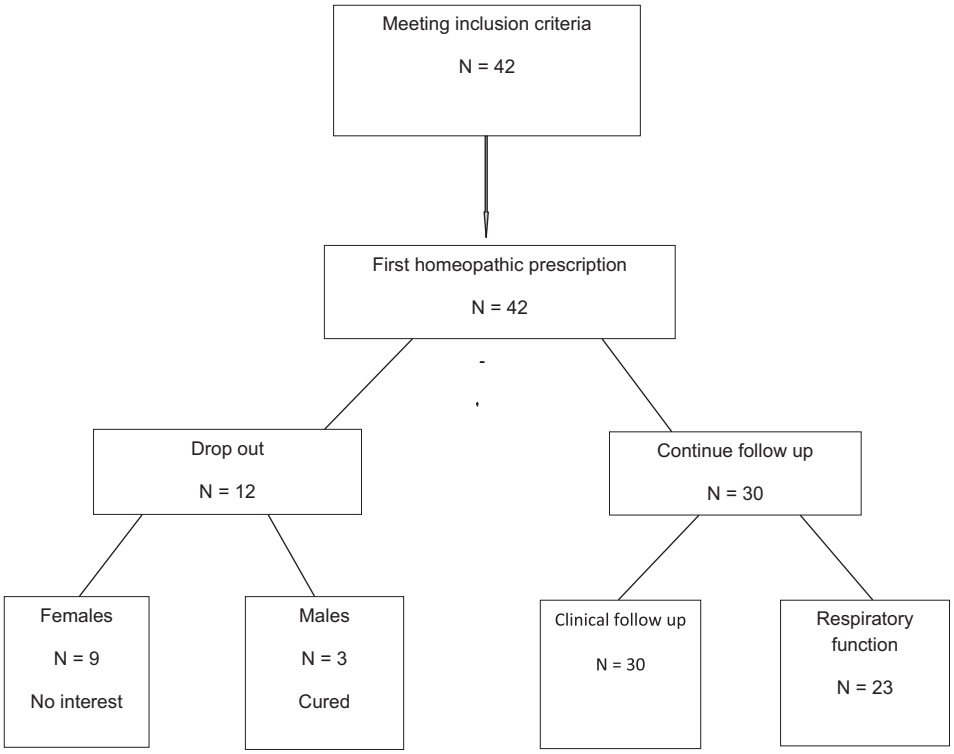

Figure 1 Flow chart of asthmatic patients included in the study.

Table 1 Patient characteristics at baseline

Age	
Mean ± SD	10.0 ± 2.3
Range	7–15
Sex	***N* (%)**
Females	9 (30%)
Males	21 (70%)
Weight (kg) (mean ± SD)	34.8 ± 14.8
Height (cm) (mean ± SD)	133.1 ± 13.1
Severity	***N* (%)**
Mild intermittent	0
Mild persistent	11 (36.6%)
Moderate persistent	11 (36.6%)
Severe persistent	8 (26.6%)
Atopic comorbidities	***N* (%)**
Dermatitis or Eczema	3 (10%)
Rhinitis or sinusitis	10 (33.3%)
Conjuntivitis	9 (30%)
Treatments in previous 2 weeks	***N* (%)**
β-agonist inhaler	12 (40%)
β-agonist + corticosteroids	8 (26.6%)
Oral bronchodilators	21 (70%)
Antihistamines	1 (3.3%)
Montelukasts	1 (3.3%)
***N* of consultations per patient**	**Patients *N* (%)**
1	0
2	2 (6.6%)
3	5 (16.6%)
4	6 (20%)
5 or more	17 (56.6%)
Total	30 (100%)
***N* of days in relation to response to treatment**	
<90 days	6 (20%)
90–180 days	17 (56.6%)
>180 days	7 (23.3%)
Total	30 (100%)

in 200C potency. Medicines prescribed for cough were: *Antimonium tartaricum*, *Blatta orientalis*, *Drosera rotundifolia*, *Euphrasia*, *Hepar sulphuris*, *Kalium bichromicum*, *Lobelia inflata*, and *Sabadilla* from *6 to 30C potency. Calcarea carbonica and Natrum muriaticum* were the most frequent polychrest medicines prescribed (33.3% of prescriptions), 17 patients (56.6%) received a simillimum plus a specific medicine. (Table 2). Ascending potencies were prescribed in acute attacks in Hahnemannian scale up to 30C in daily doses. Higher potencies (200C) were used between attacks in single doses. No aggravations of symptoms were reported.

Patients reduced ICS from about 1 month after stopping short acting inhalers spontaneously due to disappearance of symptoms following the protocol of Colin.[27] There was a modest but statistically significant withdrawal of conventional treatment comparing first and last consultations (Tables 3 and 4).

Outcomes

At the beginning of the study, all children suffered from persistent asthma: 11 (36.6%) had mild, 11 (36.6%) had moderate and eight patients (26.6%) had severe persistent asthma i.e. no patient was suffering from intermittent asthma. Frequency distribution of symptoms at the beginning of the study, 3 & 6 months after homeopathy were shown in Table 3. Frequency of symptoms, night awakening, inhaler usage and oral corticosteroid usage were significantly regressed 3 and 6 months after homeopathy (Table 4).

Table 2 Homeopathic medicines prescribed

Polychrests (200C)	*3 months* N *(%)*	*6 months* N *(%)*
Calc. carb.	5 (16.6%)	4 (13.3%)
Natrum mur	5 (16.6%)	3 (10%)
Lycopodium	3 (10%)	0
Silicea	3 (10%)	0
Arsenicum Album	2 (6.6%)	1 (3.3%)
Calc. phos.	2 (6.6%)	4 (13.3%)
Natrum sulph	2 (6.6%)	0
Tuberculinum	2 (6.6%)	3 (10%)
Cuprum	1 (3.3%)	1 (3.3%)
Hyoscyamus	1 (3.3%)	1 (3.3%)
Phosphorus	1 (3.3%)	2 (6.6%)
Pulsatilla	1 (3.3%)	0
Sulphur	1 (3.3%)	1 (3.3%)
Thuja	1 (3.3%)	0
Baryta carb.	0	1 (3.3%)
Lachesis	0	1 (3.3%)
Merc. Sol.	0	1 (3.3%)
Total: 30 patients	30 (100%)	23 (76.6%)
Symptomatic (6-30C)		
Hepar sulph	5 (16.6%)	2 (6.6%)
Antimonium Tart	4 (13.3%)	4 (13.3%)
Drosera	3 (10%)	2 (6.6%)
Kalium bich	2 (6.6%)	8 (26.6%)
Blatta	1 (3.3%)	0
Lobelia	1 (3.3%)	2 (6.6%)
Sabadilla	1 (3.3%)	0
Total: 30 patients	17 (56.6%)	18 (60%)

No significant improvement was shown in the pulmonary functions, except VC at 3 months after starting homeopathic treatment. However all parameters of pulmonary function, except FEV1/FVC, were significantly improved at 6 months (Table 5).

Table 3 Descriptive statistics of asthmatic patients basal, 3 and 6 months after homeopathy

Variables	*Basal*		*3 months*		*6 months*	
	N	%	N	%	N	%
Frequency of symptoms						
<Twice/week	2	6.7	4	13.3	17	56.7
>Twice/week	12	40	12	40	11	36.7
Daily	9	30	13	43.3	2	6.7
Through the day	7	23.3	1	3.3	0	0
Night awakening						
Once or twice/month	13	43.3	4	13.3	17	56.7
Three or four/month	7	23.3	14	46.7	12	40.0
>Once/week	10	33.3	12	40.0	1	3.3
Nightly	–	–	–	–	–	–
Inhaler usage						
<Twice/week	2	6.7	2	6.7	15	50.0
>Twice/week	12	40.0	15	50.0	13	43.3
Daily	6	20.0	12	40.0	2	6.3
Through the day	10	33.3	1	3.3	–	–
Oral corticosteroids courses						
0–1	3	10.0	29	96.7	27	90.0
>2	27	90.0	1	3.3	3	10.0
Total score						
Mild intermittent	–	–	–	–	11	36.7
Mild persistent	11	36.6	17	56.7	17	56.7
Moderate persistent	11	36.6	13	43.3	2	6.7
Severe persistent	8	26.6	–	–	–	–

Table 4 Symptom rating after 3 and 6 months of homeopathic treatment

Variables	*3 months*				*6 months*			
	Improved	*Unchanged*	*Worse*	P-*value*[a]	*Improved*	*Unchanged*	*Worse*	P-*value*[a]
	N *(%)*	N *(%)*	N *(%)*		N *(%)*	N *(%)*	N *(%)*	
Frequency of symptoms	10 (33.3)	20 (66.6)	0 (0)	0.002	27 (90)	3 (10)	0 (0)	0.0001
Night awakening	19 (63.3)	11 (36.7)	0 (0)	0.0001	30 (100)	0 (0)	0 (0)	0.0001
Inhaler usage	12 (40)	18 (60)	0 (0)	0.001	27 (90)	3 (10)	0 (0)	0.0001
Corticosteroid use	26 (86.7)	4 (13.3)	0 (0)	0.0001	24 (80)	6 (20)	0 (0)	0.0001

[a] Paired Wilcoxon test.

Discussion

This is the first study to observe the effect of classical homeopathy in Egypt and in asthma. Homeopaths were free to practice in their usual way, combining homeopathic prescriptions with conventional treatment. We believe it is important to test homeopathy in the form in which it is commonly practiced rather than in a form specially modified for clinical trials. We also felt that it was important to include more than one homeopath in the study.

Although an observational study is considered relatively low grade of evidence, it has the advantage of showing what happens in the routine medical setting. Moreover, some issues about the study model and the patients' characteristics might heighten the value of this type of research. Respiratory complaints generally seem to respond well to homeopathic treatment, and success rates are better for patients under the age of 15.[28]

All cases in our study had persistent asthma and were on conventional treatment. Response to homeopathic treatment was strongly positive in most of them. Although there were no controls in this study, the overall positive result in the respiratory tests after 6 months was similar to that for ICS in randomised controlled trials (RCTs). Several placebo-controlled trials among children 4−11 years of age compared fluticasone with placebo during a 12-week, double-blind period. After 12 weeks, the improvement in FEV1 for patients receiving 100 μg of fluticasone twice per day was 0.23L, 0.25L and 0.27L with little placebo effect.[29−31] Our study showed a significant increase of 0.21L in FEV1(13%) after 6 months of treatment with homeopathic medicines. Other respiratory tests as VC, FVC, PEF(25−75) and PEF, increased respectively by 15.8%, 12.5%, 16.6% and 13.4%.

At the beginning of the study, all children were suffering from persistent asthma (mild, moderate or severe) no one had intermittent asthma. After 3 months of treatment with homeopathy in adjunct with conventional medications, relative significant improvement occurred in the clinical condition and in severity of some cases but spirometry did show some insignificant improvement. After 6 months of homeopathic treatment and gradual withdrawal of medications 11 (36.7%) children shifted to intermittent asthma and 17 (56.7%) children shifted from severe to moderate or mild persistent or intermittent asthma. At the end of study, no child was suffering from severe persistent asthma.

During the first 3 months of treatment no child suffered deterioration of symptoms, symptoms were either stationary or improved. After 6 months of homeopathic treatment all children were able to sleep normally, 27 (90%) of children had no attacks of cough, 27 (90%) children did not need β-agonist inhalers and 24 children (80%) did not require oral corticosteroids.

The significant regression of asthma attacks frequency and the reduction of inhalers usage in 90% of patients after 6 months of homeopathy treatment is consistent with that in previously published observational studies: 74% Rossi,[28] 89% Wassenhoven;[32] 78% Robinson;[33] 70.7% Spence.[34] The numbers who did not respond to treatment are also similar (10% in this study; 9% in Rossi;[28] 8.5% in Wassenhoven[32]). Drop-out incidence in our study (28.5%) was similar to that reported in other published observational studies of homeopathy (38.1% and 55.9%).[28,35] In our study the percentage of patients lost to follow-up was lower among males than females (Figure 1).

The question of how much time is needed to observe a clinically significant response in patients with asthma was addressed. Short observation times are thought to be

Table 5 Pulmonary function of asthmatic patients before, 3 and 6 months after homeopathy

Variables	*Before treatment mean ± SD*	*After 3 months mean ± SD*	*After 6 months mean ± SD*	P-*value Before v 3 months*[a]	P-*value Before v 6 months*[a]
VC (%)	76.5 ± 18.8	85.7 ± 22.6	92.3 ± 16.2	0.01	0.0001
FVC (%)	72.2 ± 16.6	73.3 ± 20.6	84.7 ± 18.6	0.7	0.002
FEV (%)	77.7 ± 17.1	78.4 ± 21.4	91.2 ± 19.7	0.8	0.003
FEV/FVC	96.8 ± 5.2	98.3 ± 3.3	97.1 ± 4.2	0.3	0.8
FEF 25−75%	85.9 ± 28.3	92.8 ± 23.0	102.5 ± 29.1	0.2	0.03
PEF (%)	63.2 ± 18.2	67.7 ± 18.4	76.6 ± 20.6	0.06	0.001

[a] *t*-test for dependent variables.

insufficient to detect clinical response. On the other hand, longer periods of study increase the risk of drop-outs and the uncertainty of spontaneous amelioration. A period of 6 months was needed by almost 80% of our patients to respond, this is in line with the findings of Witt *et al.* in chronic disease treated with homeopathy.[36] Our results showed greater therapeutic effect in young patients. Witt *et al.*[36], analyzing pediatric quality of life data separately from adult data, reached a similar conclusion: young patients and patients with more serious illnesses are more likely benefit from homeopathy. This finding seems to be important in the light of some publications in the Italian Press which reported negative conclusions or even reasons for concern regarding the use of homeopathy, above all in children: in 2001, the National Bioethics Committee stated that non-conventional medicine was acceptable "*only in marginal and essentially harmless situations*".

In our study, all prescriptions were targeted to the simillimum (totality of symptoms). In Rossi's study,[28] 73% of prescriptions were "*targeted to the pathology*" (modalized symptoms, key notes, and organ affinity) in contrast to 19% of prescriptions "*based on the patient*" or on the totality of symptoms; in Wassenhoven's study,[32] 68% of prescriptions related to the overall picture and 18% were symptomatic. An unexpected result was the preeminence of the prescription of *Calcarea carbonica* (16.6%) and *Natrum muriaticum* (16.6%) at the first consultations, surprisingly *Arsenicum album* was prescribed only for two patients (6.6%). Another unexpected result was the absence of aggravation both in new medicines or rising potency. The only reaction was the appearance of transient skin papules which disappeared in 24 h only in one patient after improvement of asthma symptoms. Other comparable data has shown some aggravations [0.3% Rossi;[28] 3.1% Spence,[34] 3% Robinson,[33] 2.4% van Wassenhoven[32] and Endrizzi, 2.68%[37]].

Our results are not in line with those of a randomised, double blind, placebo-controlled trial testing the effects of individualised homeopathic medicines in comparison with placebo medication in children with asthma as an adjunct to conventional treatment. There were relative improvements in severity, but the sizes of the effects were small.[38] The main weaknesses of this study were the mildness of the asthma, resulting in a 'ceiling effect'. The children in our study were much more seriously affected.

Our results suggest that homeopathic therapy can be combined with conventional pharmacological treatment. This finding seems to contradict the view widely held in homeopathic circles that conventional treatment previous to, or in association with, homeopathic treatment reduces the probability of success.

Limitations

This is a longitudinal observational study with no control group and suffers from the limitations of such studies. There are possible biases relating to differential drop out, regression to the mean, non-specific and placebo effects, and the doctor−patient relationship in the subjective evaluation of the symptoms on the part of the patients and their parents.

Conclusion

This study suggests that in a general pediatric practice setting, homeopathic treatment may be effective for children with asthma. Controlled studies should be conducted.

Conflicts of interest

None declared.

Acknowledgments

The authors thank Dr Magda El Mahgary for her help and support with this study. We also thank the following pediatricians and physicians at the department for their help in following up children and in data entry: Dr Ehab Kamal, Dr Mona Samir, Dr Inas Mahfouz and Dr May Seoudi.

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