



Home telemonitoring (forced expiratory volume in 1 s) in children with severe asthma does not reduce exacerbations

A. Deschildre*, L. Béghin[#], J. Salleron[†], C. Iliescu[#], C. Thumerelle*, C. Santos*, A. Hoorelbeke⁺, M. Scalbert[§], G. Pouessel[‡], M. Gnansounou**, J.-L. Edmé^{###} and R. Matran^{###}

ABSTRACT: Some children with severe asthma develop frequent exacerbations despite intensive treatment.

We sought to assess the outcome (severe exacerbations and healthcare use, lung function, quality of life and maintenance treatment) of a strategy based on daily home spirometry with teletransmission to an expert medical centre and whether it differs from that of a conventional strategy.

50 children with severe uncontrolled asthma were enrolled in a 12-month prospective study and were randomised into two groups: 1) treatment managed with daily home spirometry and medical feedback (HM) and 2) conventional treatment (CT).

The children's mean age was 10.9 yrs (95% confidence interval 10.2–11.6). 44 children completed the study (21 in the HM group and 23 in the CT group). The median number of severe exacerbations per patient was 2.0 (interquartile range 1.0–4.0) in the HM group and 3.0 (1.0–4.0) in the CT group ($p=0.38$ with adjustment for age). There were no significant differences between the two groups for unscheduled visits (HM 5.0 (3.0–7.0), CT 3.0 (2.0–7.0); $p=0.30$), lung function (pre- β_2 -agonist forced expiratory volume in 1 s (FEV₁) $p=0.13$), Paediatric Asthma Quality of Life Questionnaire scores ($p=0.61$) and median daily dose of inhaled corticosteroids ($p=0.86$).

A treatment strategy based on daily FEV₁ monitoring with medical feedback did not reduce severe asthma exacerbations.

KEYWORDS: Child, control, exacerbation, forced expiratory volume in 1 s, severe asthma, telemonitoring

Some children with severe asthma remain uncontrolled and develop frequent exacerbations despite intensive treatment according to guidelines [1]. High healthcare use, including hospitalisation, is a characteristic of these patients [2]. The addition of home peak expiratory flow monitoring to a symptom-based self-management plan does not improve asthma outcome [3–5]. Preliminary studies have demonstrated the feasibility of using a spirometer or peak flow meter and recording data, which are transferred *via* telephone or internet to medical personnel. Data may indicate the need for medical intervention that is promptly made either over the telephone or internet. This new approach is called telemedicine [6]. We hypothesised that a daily monitoring of spirometry with professional feedback could improve asthma control, and prevent exacerbations. We stated that forced expiratory volume in 1 s (FEV₁), the gold standard for airway obstruction assessment, may be a better measure than peak expiratory flow for

early detection of loss of control and risk of exacerbation [7].

The aim of this study was to assess the outcome of a treatment strategy based on daily home spirometry, with teletransmission to an expert medical centre, in children and adolescents with severe uncontrolled asthma. This management strategy was compared with conventional treatment in the form of a randomised clinical trial over a period of 1 yr. Primary outcome was the frequency of severe exacerbations and unscheduled healthcare use. Lung function, quality of life and maintenance treatment were also assessed.

MATERIALS AND METHODS

Study design

We carried out a 12-month, prospective, randomised, controlled study of two groups of children. In one group, treatment was adjusted according to daily home telemonitoring of spirometry (HM

AFFILIATIONS

*Unité de Pneumologie-Allergologie Pédiatrique, Clinique de Pédiatrie Jeanne de Flandre, CHRU de Lille and Université Nord de France,

[#]CIC-9301-Inserm-CHU (Centre d'Investigation Clinique de Lille), CHRU de Lille & U995 Inserm, and Université Nord de France,

[†]Département de Biostatistiques, CHRU de Lille and Université Nord de France,

^{###}Explorations Fonctionnelles Respiratoires Pédiatriques, CHRU de Lille and Université Nord de France, Lille,

⁺Association Santély, Loos,

[§]Service de Pédiatrie, Centre Hospitalier de Dunkerque,

Dunkerque,

[‡]Service de Pédiatrie, Centre Hospitalier de Roubaix, Roubaix, and

**Service de Pédiatrie, Centre Hospitalier Sambre-Avesnois, Maubeuge, France.

CORRESPONDENCE

A. Deschildre
Unité de Pneumologie-Allergologie Pédiatrique

Clinique de Pédiatrie Jeanne de Flandre
CHRU
59037 Lille cedex
France
E-mail: antoine.deschildre@chru-lille.fr

Received:

Dec 01 2010

Accepted after revision:

July 13 2011

First published online:

Aug 18 2011

European Respiratory Journal
Print ISSN 0903-1936
Online ISSN 1399-3003

group, n=21). The other group was monitored by conventional treatment according to recommended guidelines (CT group, n=23). Patients were recruited at the Paediatric Pulmonary Unit, Hôpital Jeanne de Flandre, University Hospital, Lille, France and at three paediatric departments in the Nord-Pas de Calais region (Roubaix, Dunkerque and Maubeuge). The Paediatric Pulmonary Function Testing Unit and the Paediatric Centre for Clinical Investigations (CIC-9301-Inserm-CHU) at Lille University Hospital were involved in the project, as well as Santély, a regional network for home care, which installed the remote monitoring equipment. The study was approved by the Lille university hospital ethics committee (CPP Nord Ouest IV, January 8, 2002; number 02/10). Parents (or legal guardians) and the child were informed of the goals and constraints of the study and all provided informed written consent before enrolment.

Data quality assurance was assumed by the Clinical Investigation Centre of Lille (CIC-9301-Inserm-CH&U). Regulatory aspects were performed by the designated "Good Clinical Practices sponsor" at University Regional Centre Hospital (CHRU).

Patients and randomisation

The study population included children aged 6–16 yrs with severe allergic asthma according to the Third Paediatric Asthma Consensus (*i.e.* frequent acute episodes requiring oral corticosteroid therapy, associated with moderate episodes (exercise-induced asthma, chronic cough, sleep disturbances, treatment with short-acting β_2 -agonists >3 times per week) and airflow limitation) [8]. All of the children had uncontrolled asthma with frequent severe exacerbations. Reversibility in FEV₁, defined as a reversibility of $\geq 12\%$ and/or an increase of at least 200 mL, was documented for all patients. Exclusion criteria were congenital or acquired chronic illnesses other than asthma.

Children were included into the study during a scheduled visit. Personal and family history, characteristics of asthma and treatments were recorded. Pulmonary function tests were performed (spirometry, before and after the administration of 400 μ g salbutamol) and lung function variables were expressed as % predicted (% pred) [9]. The socioeconomic status of the children's families was analysed by using parental occupation, as described in the International Standard Classification of Occupation (<http://unstats.un.org/unsd/class/family/family2.asp?Cl=224>). ISCO is a hierarchical scale specifically developed to be used as a nine-class classification of occupations, where 1 is the highest and 9 the lowest category. For the study, we used the mean of father's and mother's scales.

Random allocation to either the HM or the CT group was performed at inclusion, resulting in groups of six patients in each investigation centre. After randomisation, investigators were not blinded concerning patients' groups (HM or CT).

Study interventions

For all patients, symptoms, rescue treatments (β_2 -bronchodilators and systemic corticosteroids), as well as any healthcare use (any unscheduled visit to either a general practitioner or emergency department and hospitalisation) were recorded by the patient and their parents on a daily paper diary. Scheduled follow-up visits occurred every 4 months. Pulmonary function tests were performed at the beginning and at the end of the study, and maintenance treatment (daily inhaled corticosteroid dose) was

recorded at the same time. Quality of life was assessed by the Paediatric Asthma Quality of Life Questionnaire (PAQLQ) [10]. The questionnaire was administered at the beginning and at the end of the study.

In the HM group, patients received instruction on how to use the spirometer. They were also instructed on how to correctly perform forced expiratory manoeuvres. They had to perform one measurement session in the morning and one in the evening, after taking their maintenance treatment. Flow-volume loops were transmitted to the hospital expert centre (Paediatric Pulmonary Function Testing Unit, Lille University Hospital, Lille) *via* a modem telephone link. Surveillance was assured 5 days out of seven, from Monday to Friday. The measurements on Saturday and Sunday were analysed on Monday morning.

The equipment used was an AM1 spirometer (Asthma Monitor; Jaeger, Geispolshelm-Gare, France) supplied with an automated modem that allowed daily transmission of spirometry data to the expert centre. The device was designed in two parts: first, a pocket-sized electronic peak flow meter (the "asthma monitor", weight 145 g, 112 \times 90 \times 25 mm) and, secondly, the modem (weight 265 g, 160 \times 100 \times 40 mm (Health Communicator HC1; Jaeger GmbH, Hoechberg, Germany)), which permitted the transfer of digital data *via* the telephone network to the expert centre. Calibration of the spirometer was performed by the device's manufacturer, as previously validated by RICHTER *et al.* [11]. Quality criteria were controlled at the beginning and the end of follow-up.

The transmitted data allowed flow-volume loops to be constructed using AMOS software (Jaeger). The available data were forced vital capacity, FEV₁, peak expiratory flow, forced expiratory flow at 25–75% of forced vital capacity (FEF_{25–75%}), expressed as % pred [9]. The FEV₁ was the parameter that we choose for daily monitoring because of its low intra-individual variability [7]. Spirometry data were analysed once a day by a well-trained physician at the expert centre and stored in a database. Any records caused by failed manoeuvre (expiration time <1 s), technical errors or unexplained outliers were invalidated and excluded from the data set.

The installation and maintenance of the remote monitoring system were performed by the Santély network. Every 4 months, all of the equipment and its use were systematically tested at the child's home. In between these periods, the expert centre or Santély could be contacted to address any technical problems associated with the equipment.

The physician at the expert centre analysed the FEV₁ data and made the following management decisions: if FEV₁ was $\geq 80\%$ pred, there was no intervention. If a decline in FEV₁ <80% pred was detected, the physician contacted the parents of the child. Asthma symptoms and rescue drugs were detailed and the treatment was adjusted according to Global Initiative for Asthma (GINA) guidelines [1]. The general practitioner was contacted, if needed, in the case of FEV₁ values of 60–80% pred. In cases of FEV₁ <60% pred, the physician judged whether a course of oral corticosteroids was rapidly required and either informed or contacted the general practitioner or the paediatrician who followed the child at the hospital.

At the end of the study, we also evaluated, by questionnaire, the opinion of the parents of the children who underwent HM. The

questionnaire asked the parents if they were satisfied with and reassured by the HM, and whether it was easier for them to manage their child's asthma.

Outcome measures

The primary outcome was the number of severe exacerbations defined by a systemic corticosteroid course during the follow-up. We also evaluated the number of days of systemic corticosteroid treatment and the healthcare use (unscheduled visit to either a physician or emergency department and hospitalisation). Secondary outcomes were the differences in maintenance treatment (daily dose of inhaled corticosteroids), lung function (FEV₁, FEF_{25–75%}, before and after administration of β_2 -agonists) and quality of life (measured by PAQLQ) at the end of the follow-up between the two groups. For these parameters, in each group, we also evaluated the differences between the beginning and the end of the study. A change in PAQLQ score of ≥ 0.5 was considered a clinically important improvement, and a change of ≥ 1.5 a large improvement.

Statistical analyses

The power calculation was based upon the number of severe exacerbations. We referred to a study at the Paediatric Pulmonary Unit at Lille University Hospital in asthmatic children admitted for asthma exacerbation, which indicated a frequency of 3.5 ± 1.43 exacerbations per year [12]. Assuming a risk α of 5%, the study was designed to have a power of 80% to detect a reduction of at least 30% in the number of severe exacerbations in the HM group compared with the GT group. Each group required 26 patients.

Quantitative variables are presented as mean (95% confidence interval) or median (interquartile range), according to the distribution and the number of subjects, and qualitative variables as frequencies and percentages. Comparisons between the HM and CT groups were performed using the Mann–Whitney U-test for quantitative variables and the Chi-squared test or Fisher's exact test for qualitative variables. Covariance analysis according to the Conover method was performed in order to adjust the result on age [13]. To assess the difference in quantitative variables between the beginning and the end of the study, the Wilcoxon test for paired sample was used. Statistical analyses were performed with SAS System V9.2 (SAS Institute Inc., Cary, NC, USA). A p-value of < 0.05 was considered significant.

For the final analysis, we only included patients with ≥ 120 days of participation in the study. Patient adherence was calculated as the percentage of days with one or with two measurement sessions per day.

RESULTS

Population

50 children, mean age 10.9 (95% CI 10.2–11.6) yrs, were included in the study between January 5, 2003 and December 31, 2007. Asthma was not controlled in all patients. 24% had been hospitalised at least twice during the previous year, and 12% had a history of intensive care unit hospitalisation for asthma. Maintenance treatment was based on inhaled corticosteroids (mean dose $1,226 \mu\text{g}$ equivalent budesonide $\cdot \text{day}^{-1}$ (95% CI 1,057–1,395)), in combination with a long-acting bronchodilator (100%), a leukotriene antagonist (38%) and nasal corticosteroids (36%). Mean pre- β_2 -agonist FEV₁ was 87.5% pred (95% CI 82.7–92.2%) and post- β_2 -agonist FEV₁ was 104.4% pred (95% CI 96.1–106.9).

The mean PAQLQ score at inclusion showed a moderate impact of asthma on quality of life (4.3 (95% CI 4.0–4.6)). There were no significant differences among the two groups, except for atopic dermatitis, which was more frequent in the HM group (table 1). Socioeconomic status was in the medium class, was similar between the two groups (mean ISCO scale: HM group = 6.1 ± 2.2 , CT group = 6.0 ± 2.3 ; $p = 0.805$) and was also similar to the general population of the Nord-Pas de Calais region (mean ISCO scale = 5.98 ± 0.9).

The participation of the patients in the study is summarised in figure 1. For the final analysis, we only included patients with ≥ 120 days of participation in the study. Six patients (four from the HM group) were excluded during the first 120 days for the following reasons: technical problems related to telemonitoring ($n = 2$), noncompliance with telemonitoring ($n = 2$) and refusal to continue with the study ($n = 2$). Nine other patients were discontinued from the study before 12 months (moving abroad with impossibility to continue the study ($n = 2$), technical problems ($n = 2$) and noncompliance ($n = 5$)). Therefore, the analysis was performed for a population of 44 children, 21 in the HM group and 23 in the CT group, among whom 35 were monitored for one full year.

Adherence to the spirometry assessments is shown in figure 2. We collected 7,419 flow–volume loops, of which 331 (4.5%) were invalid (expiration time < 1 s). We observed that most patients did one but not two measurement sessions per day. There was no association between patient age and adherence to spirometry ($p = 0.29$).

Primary outcome

Among the 44 children, only four (two from the HM group and two from the CT group) had no severe exacerbation, whereas 25 patients (10 from the HM group and 15 from the CT group) had > 2 severe exacerbations. The risk of exacerbation was inversely related to age ($r = -0.41$; $p = 0.0057$). In the HM group, the median (interquartile range) number of severe exacerbations per patient was 2.0 (1.0–4.0) compared with 3.0 (1.0–4.0) in the CT group ($p = 0.38$, with adjustment for age). There was also no significant difference between the two groups for the number of days of treatment with systemic corticosteroids; the median (interquartile range) treatment time in the HM group was 10.0 (5.0–17.0) days and in the CT group was 12.0 (4.0–22.0) days; $p = 0.88$), for unscheduled visits in the HM group was 5.0 (3.0–7.0) visits and in the CT group was 3.0 (2.0–7.0) visits ($p = 0.30$), and for hospitalisation (two patients in each group; $p = 0.94$) (table 2). The results were unchanged for the 35 patients who were followed-up for 1 yr.

Secondary outcomes

At the end of the follow-up, there were no significant changes between the two groups for either the median dose of inhaled corticosteroids ($p = 0.86$) or lung function ($p = 0.07$ for post- β_2 -agonist FEV₁) (table 2). Concerning quality of life, no significant difference between the two groups was observed at the end of the study (median in HM group 4.5 (0.0–5.1) and median in CT group 3.9 (0.0–5.1); $p = 0.61$) (table 3). Four patients improved their PAQLQ total score by at least 1.5 points (three in the HM group and one in the CT group; $p = 0.33$).

At the end of the follow-up, we also did not observe significant changes from baseline in each group for pre- and post- β_2 -agonist

TABLE 1 Patients' characteristics at baseline

	HM	CT
Subjects n	25	25
Age yrs	11.0 (9.3–12.4)	11.2 (8.4–13)
Males	18 (72)	19 (76)
Duration of asthma yrs	6.0 (3.3–8.3)	4.3 (3.2–5.2)
≥2 hospitalisations for asthma during the past year	7 (28)	5 (20)
Ever ICU admission	4 (16)	2 (8)
Pre-β₂-agonist FEV₁ % pred	87.4 (79.9–103.0)	83.3 (72.4–96.2)
Pre-β₂-agonist FEF_{25–75%} % pred	53.6 (41.1–73.7)	51.3 (37.5–68.9)
Post-β₂-agonist FEV₁ % pred	110 (101–112)	103 (95–108)
Post-β₂-agonist FEF_{25–75%} % pred	84 (69–95)	81 (66–100)
ICS dose μg equivalent BUD·day⁻¹	1000 (800–1200)	1200 (800–2000)
PAQLQ overall score	4.2 (3.7–4.8)	4.2 (3.4–5.3)
PAQLQ domains		
Symptoms	3.8 (3.4–4.7)	4.0 (3.1–5.0)
Activities	3.6 (3.2–4.2)	4.0 (2.6–4.8)
Emotions	4.9 (4.2–6.1)	5.1 (3.9–6.4)
Other allergic features		
Rhinitis	10 (40)	11 (44)
Eczema	14 (58)	7 (28)
Food allergy	5 (21)	3 (12.5)

Data are presented as median (interquartile range) or n (%), unless otherwise stated. HM: home monitoring, CT: conventional treatment; ICU: intensive care unit; FEV₁: forced expiratory volume in 1 s; % pred: % predicted; FEF_{25–75%}: forced expiratory flow at 25–75% of forced vital capacity; ICS: inhaled corticosteroids; BUD: budesonide; PAQLQ: Paediatric Asthma Quality of Life Questionnaire.

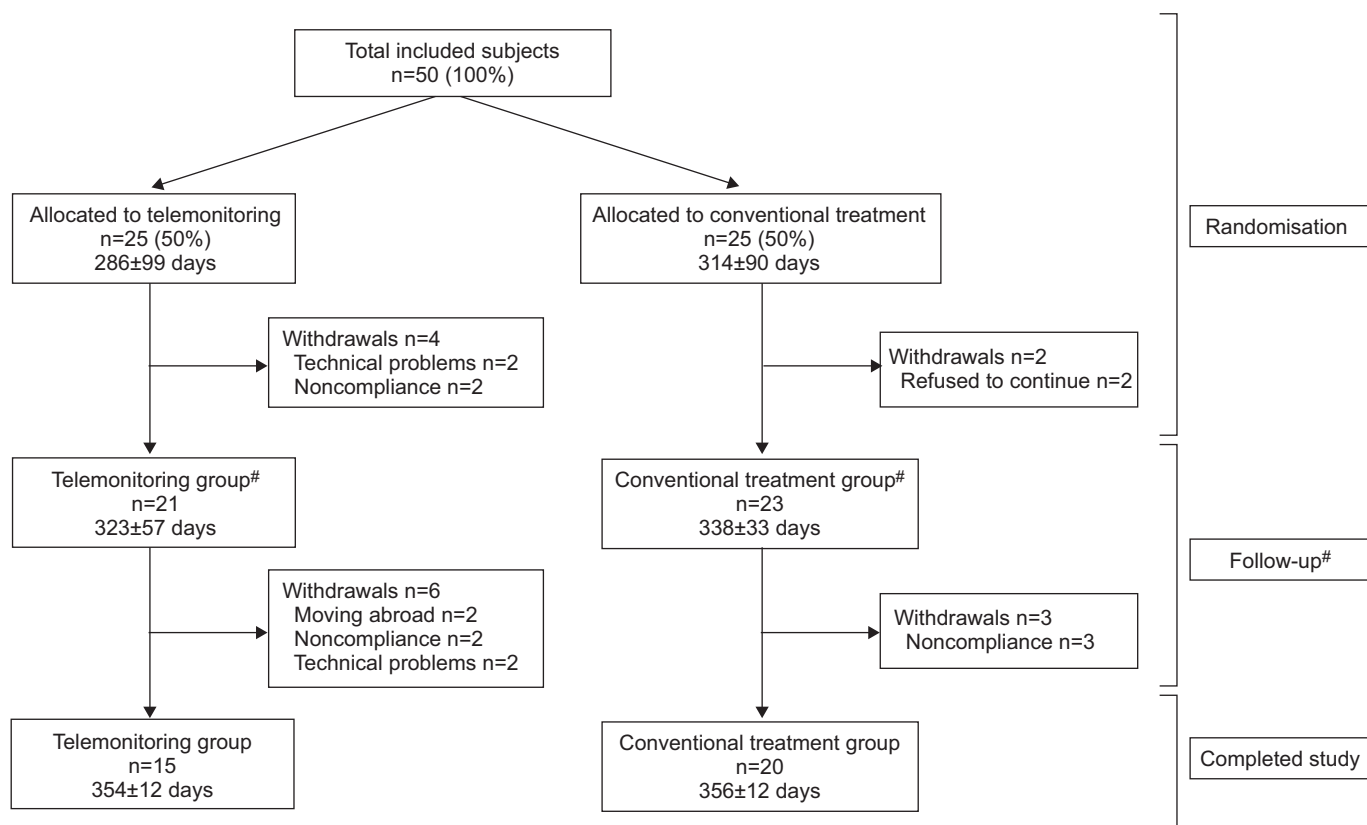


FIGURE 1. Summary of patients participating in the study. #: >120 days participation in the study.

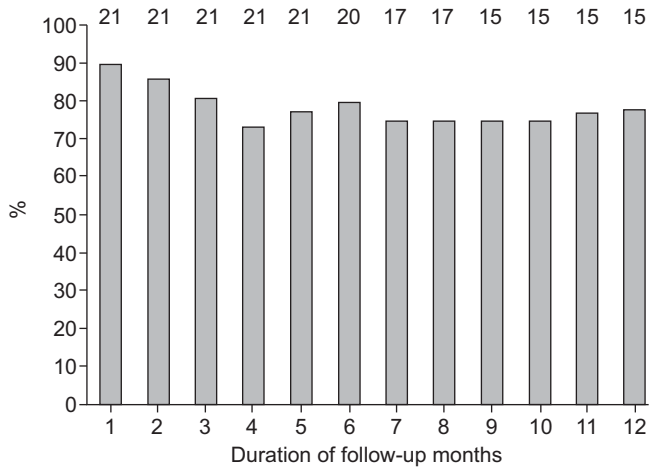


FIGURE 2. Average values for patient adherence with monitoring (at least one session per day) as a function of follow-up time. Figures over the bars refer to the number of patients studied at each time-point.

FEV1 and FEF25–75%. There were no significant changes in PAQLQ scores within each of the two groups (median in the HM group was -0.3 (-4.2–1.1) (p=0.24) and in the CT group was -0.1 (-3.8–0.5) (p=0.15)). Decrease in activities (p=0.02) and symptoms (p=0.05) domain scores reached statistical significance in the CT group (table 4).

All the results were unchanged for the 35 patients who were followed-up for 1 yr.

Finally, the analysis of the parents’ responses to the questionnaire for the HM group showed that they were satisfied with the monitoring of respiratory function (57.1% were very satisfied and 33.1% satisfied *versus* 9.5% who were not satisfied). They felt generally reassured (57.1% felt very reassured and 42.9% reassured *versus* 0% who were not reassured). Parents believed that the monitoring was generally easy to carry out (57.1%

thought it very easy and 38.1% easy *versus* 4.8% who thought it was not easy to carry out).

DISCUSSION

In children with severe uncontrolled asthma, the hypothesis that daily home telemonitoring of FEV1 would be superior to conventional management in terms of severe exacerbations and healthcare use received no support from the present study. There was also no significant difference for inhaled corticosteroid maintenance treatment, lung function and quality of life.

When monitoring lung function, the aim is to obtain an objective parameter to guide asthma treatment. We stated that FEV1, the gold standard for airway obstruction assessment with a good reproducibility, may be a better measure than peak expiratory flow for early detection of loss of asthma control and risk of exacerbation. Indeed, peak expiratory flow provides an insensitive assessment of airway obstruction. Clear modifications of peak expiratory flow are not necessarily associated with any alteration in FEV1, and exacerbations of asthma are observed without any change in peak expiratory flow [14]. Studies do not support the hypothesis that routine peak expiratory flow monitoring is better than monitoring of overall symptoms as an asthma self-management plan, either in adults or in children [3–5].

We postulated that daily transmission of flow–volume loops to an expert centre and FEV1 monitoring allows for a more accurate follow-up of the disease and a close relationship between patients and physicians with telephone contact, as well as educational interventions. We could not confirm this hypothesis. In the same way, BROUWER *et al.* [15] demonstrated that FEV1 monitoring was not an efficient tool in mild-to-moderate asthma. In their study, 36 children reported a daily symptom score in a diary and blindly measured spirometry. Symptoms were treated according conventional guidelines. The results were collected each month during a scheduled visit. The authors demonstrated a poor correlation between the pulmonary function test assessments (peak expiratory flow and FEV1) and the symptom scores.

TABLE 2 Exacerbations and healthcare use in the follow-up year and lung function and daily dose of inhaled corticosteroids at the end of the follow-up

	HM	CT	p-value
Subjects n	21	23	
Severe exacerbations[#] n per patient	2.0 (1.0–4.0)	3.0 (1.0–4.0)	0.38
Duration of treatment with systemic corticosteroids days per patient	10.0 (5.0–17.0)	12.0 (4.0–22.0)	0.88
Unscheduled visits n per patient	5.0 (3.0–7.0)	3.0 (2.0–7.0)	0.30
Lung function			
Pre-β ₂ -agonist			
FEV1 % pred	95.4 (89.3–104.8)	90.1 (74.6–97.3)	0.13
FEF25–75% % pred	63.6 (60.0–70.7)	66.0 (47.2–77.7)	0.76
Post-β ₂ -agonist			
FEV1 % pred	105.2 (98.8–97.3)	96.2 (85.4–107.0)	0.07
FEF25–75% % pred	85.7 (68.4–97.7)	77.1 (62.8–95.6)	0.44
ICS dose µg equivalent BUD·day⁻¹	1000 (800–1200)	1200 (800–2000)	0.86

Data are presented as median (interquartile range), unless otherwise stated. HM: home monitoring; CT: conventional treatment; FEV1: forced expiratory volume in 1 s; % pred: % predicted; FEF25–75%: forced expiratory flow at 25–75% of forced vital capacity; ICS: inhaled corticosteroids; BUD: budesonide. [#]: adjusted for age.

TABLE 3 Median Paediatric Asthma Quality of Life Questionnaire scores at the end of the study in each group

	HM	CT	p-value
Subjects n	21	23	
Symptoms	4.0 (0–5.0)	3.0 (0–5.0)	0.84
Activities	3.6 (0–4.4)	3.4 (0–4.0)	0.67
Emotions	5.1 (0–7.0)	5.0 (0–6.4)	0.64
Overall	4.5 (0–5.1)	3.9 (0–5.1)	0.61

Data are presented as median (interquartile range), unless otherwise stated.
HM: home monitoring; CT: conventional treatment.

Correlation was good for only 19.5% of the patients. The authors concluded that, among patients with mild-to-moderate asthma, there was no evidence that treatment should be adapted according to a daily measure of FEV₁. Recently, using daily home spirometry (measuring peak expiratory flow and FEV₁) for 8 weeks in 51 children with mild-to-moderate asthma, BROUWER *et al.* [16] investigated change in lung function during respiratory symptoms prompting reliever therapy. They showed highly variable peak expiratory flow and FEV₁ values at times of symptoms and a complete overlap in distributions between symptom-free days and at times of symptoms. This discrepancy between symptoms and lung function may help to explain the outcome of our study.

A small number of studies on lung function telemonitoring in asthmatic patients have been published. They principally concerned peak expiratory flow measures transmission in adult patients with asthma of varying severity. FINKELSTEIN *et al.* [17] confirmed the feasibility of spirometry self-assessment for asthma telemonitoring *via* internet in 31 asthmatic adults; however, they did not report the effects on disease control. Also studying adults, KOKUBU *et al.* [18] demonstrated the effectiveness of remote monitoring of peak expiratory flow combined with an educational programme on the occurrence of exacerbations requiring emergency department visits or hospitalisation. More recently, RASMUSSEN *et al.* [19] established a management programme for asthma *via* the internet that included daily measurements of peak expiratory flow and symptoms recorded in an electronic diary. Treatment instructions for the patient were based on peak expiratory flow values and data were transmitted to a physician who adjusted the treatment. This was compared with conventional asthma treatment in accordance with the standard Danish guidelines by either a general practitioner or a hospital specialist. The authors evaluated symptoms, lung function (FEV₁), airway responsiveness to metacholine and quality of life (asthma Quality of Life Questionnaire). For each management group, 100 adults aged 18–45 yrs with moderate-to-severe asthma were recruited; in total, 225 subjects completed the 6 months' study. They observed a significant improvement in all criteria in the internet-based monitoring group compared with the group managed by a general practitioner or hospital specialist. Nevertheless, they also noted that there were more unscheduled visits and higher doses of inhaled corticosteroid treatment in the internet-based monitoring group. Again, this may highlight the weakness of the

TABLE 4 Median change in Paediatric Asthma Quality of Life Questionnaire scores from baseline during the course of the study in each group

	HM	CT
Subjects n	21	23
Symptoms	-0.6 (-3.7–0.6); p=0.06	-0.9 (-3.9–0.9); p=0.05
Activities	-0.6 (-3.6–1.2); p=0.24	-0.8 (-3.6–0.6); p=0.02
Emotions	0.1 (-4.5–1.2); p=0.33	0.1 (-4–1); p=0.37
Overall	-0.3(-4.2–1.1); p=0.24	-0.1 (-3.8–0.5); p=0.15

Data are presented as median (interquartile range), unless otherwise stated.
HM: home monitoring; CT: conventional treatment.

correlation between lung function and symptoms and the risk of overtreatment in some patients.

In our study, there was no significant difference in clinical (severe exacerbations), functional (FEV₁ and FEV_{25–75%}) and treatment (daily inhaled corticosteroids dose) outcome. PAQLQ is a validated questionnaire, sensitive to small changes in quality of life over time, within and among children. It provides a more sensitive approach, incorporating all the domains of asthma impairment. This clearer picture of individual patients' overall disease status augments the traditional efficacy data [10]. However, we also did not observe any improvement in quality of life. Conversely, parents tended to evaluate telemonitoring very positively, and were reassured by the process and the link with the physician. This highlights the educational aspect of the procedure, which allowed parents to learn how to manage treatment of the asthmatic symptoms and the exacerbations, and the reassuring aspect of "telenursing". However, the children found no improvement in their quality of life despite the additional effort required to perform spirometry tests each day.

There are some limitations to our study. First, the unblinded investigators are a potential bias; however, this would tend to favour the telemonitoring group and still the outcome was negative. The process could be conducted for >120 days in only 44 patients, and for one full year in 35 patients. Technical problems and noncompliance were the main reasons for dropping out and exclusion from statistical analysis. Concerning the adherence to home spirometry, we did not distinguish between morning and evening measurements, but we observed that the majority of patients did one but not two sessions a day. The average adherence (≥ 1 session a day) decreased during the first 4 months and then remained acceptable at 75–80%. Another limitation of our study was the lack of data on diurnal variability of FEV₁ and there was no distinction between morning and evening sessions. This could be a bias in a few children. However, the fact that spirometry was performed after maintenance treatment, including the use of long-acting β_2 -agonists and inhaled corticosteroids for all patients, could have reduced the variability. The question of reproducibility of flow–volume loops has also to be discussed. REDDEL *et al.* [20] evaluated home spirometry

assessments in 33 adults with uncontrolled asthma who had completed the first 9 weeks of a clinical trial of budesonide [20]. The authors reported an excellent reproducibility based on the American Thoracic Society (ATS) criteria for FEV₁, forced vital capacity and peak expiratory flow. They also pointed out that nonrespiratory events can affect the quality of the test results. There are a few paediatric studies with spirometry assessments performed at home [21, 22]. WENSLEY and SILVERMAN [21] evaluated the ability of children aged 7–11 yrs to perform spirometry tests at home, without medical supervision [21]. This randomised controlled trial included 90 children with asthma of varying severity (24% were more than stage 2 according to the British Thoracic Society guidelines) and lasted for 16 weeks. Spirometry tests were recorded blindly for all of the patients. These assessments demonstrated a good quality of spirometry assessments in 81.9% of subjects in the first month of the study and 80.1% of subjects in the last month. There was a large variability in compliance, between 30 and 96%, with an average of 81% in the first month and 70% in the third month, indicating a significant reduction towards the end of the study. PELKONEN *et al.* [22] demonstrated that children aged 5–10 yrs with a recent diagnosis of asthma were able to perform reproducible and valid spirometry tests at home. MORTIMER *et al.* [23] demonstrated that portable spirometers could provide measurements that were highly comparable to those obtained from “gold standard” laboratory spirometers, and high-quality tracings could be achieved both at home and in the office setting. In this study [23], 92 asthmatic children aged 6–11 yrs were enrolled to evaluate the effects of pollution on respiratory health (the Fresno Asthmatic Children’s Environment Study (FACES) study). The authors showed a high agreement for peak expiratory flow and FEV₁ and, to a lesser extent, for forced vital capacity and FEF_{25–75%}.

In conclusion, we postulated but could not demonstrate that FEV₁ home telemonitoring may improve severe exacerbations and healthcare use in children with severe uncontrolled asthma. The poor performance of this intensive management pleads against telemonitoring with medical feedback. This position is now supported by the latest ATS recommendations [24].

SUPPORT STATEMENT

Financial support was provided by a grant from the French Ministry of Health “PHRC”: (N°2001/R1923/APR).

STATEMENT OF INTEREST

A statement of interest for A. Deschildre can be found at www.erj.ersjournals.com/site/misc/statements.xhtml

ACKNOWLEDGEMENTS

The authors thank the children and their parents who took part in this study.

REFERENCES

- 1 Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2011). National Institutes of Health. www.ginasthma.com. Date last accessed: November 28, 2011.
- 2 Fuhrman C, Delacourt C, De Blic J, *et al.* Hospital admissions for asthma exacerbation in children. *Arch Pediatr* 2010; 17: 366–372.
- 3 Wensley D, Silverman M. Peak flow monitoring for guided self-management in childhood asthma: a randomized controlled trial. *Am J Respir Crit Care Med* 2004; 170: 606–612.
- 4 Kotses H, Harver A, Humphries CT. Home monitoring in asthma self-management. *J Asthma* 2006; 43: 649–655.
- 5 Buist AS, Vollmer WM, Wilson SR, *et al.* A randomized clinical trial of peak flow *versus* symptom monitoring in older adults with asthma. *Am J Respir Crit Care Med* 2006; 174: 1077–1087.
- 6 Scalvini S, Vitacca M, Paletta L, *et al.* Telemedicine: a new frontier for effective healthcare services. *Monaldi Arch Chest Dis* 2004; 61: 226–233.
- 7 Nève V, Edmé JL, Devos P, *et al.* Spirometry in 3–5-year-old children with asthma. *Pediatr Pulmonol* 2006; 41: 735–743.
- 8 Warner JO, Napitz CK. Third international pediatric consensus statement on the management of childhood asthma. *Pediatr Pulmonol* 1998; 25: 1–17.
- 9 Quanjer Ph H, Stocks J, Polgar G, *et al.* Compilation of reference values for lung function measurements in children. *Eur Respir J* 1989; 2: Suppl. 4, 184s–261s.
- 10 Juniper EF, Guyatt GH, Feeny DH, *et al.* Measuring quality of life in children with asthma. *Qual Life Res* 1996; 5: 535–546.
- 11 Richter K, Kannies F, Mark B, *et al.* Assessment of accuracy and applicability of a new electronic peak flow meter and asthma monitor. *Eur Respir J* 1998; 12: 457–462.
- 12 Thumerelle C, Deschildre A, Bouquillon C, *et al.* Role of viruses and atypical bacteria in exacerbations of asthma in hospitalized children: a prospective study in the Nord-Pas de Calais region (France). *Pediatr Pulmonol* 2003; 35: 75–82.
- 13 Conover WJ, Iman RL. Rank transformations as a bridge between parametric and nonparametric statistics. *American Statistician* 1981; 35: 124–129.
- 14 Brand PL, Roorda RJ. Usefulness of monitoring lung function in asthma. *Arch Dis Child* 2003; 88: 1021–1025.
- 15 Brouwer AF, Roorda RJ, Brand PL. Home spirometry and asthma severity in children. *Eur Respir J* 2006; 28: 1131–1137.
- 16 Brouwer AF, Brand PL, Roorda RJ, *et al.* Airway obstruction at time of symptoms prompting use of reliever therapy in children with asthma. *Acta Paediatr* 2010; 99: 871–876.
- 17 Finkelstein J, Cabrera MR, Hripcsak G. Internet-based home asthma telemonitoring: can patients handle the technology? *Chest* 2000; 117: 148–155.
- 18 Kokubu F, Suzuki H, Sano Y, *et al.* Tele-medicine system for high-risk asthmatic patients. *Aerugi* 1999; 48: 700–712.
- 19 Rasmussen LM, Phanareth K, Nolte H, *et al.* Internet-based monitoring of asthma: a long-term, randomized clinical study of 300 asthmatic subjects. *J Allergy Clin Immunol* 2005; 115: 1137–1142.
- 20 Reddel HK, Ware SI, Salome CM, *et al.* Pitfalls in processing home electronic spirometric data in asthma. *Eur Respir J* 1998; 12: 853–858.
- 21 Wensley DC, Silverman M. The quality of home spirometry in school children with asthma. *Thorax* 2001; 56: 183–185.
- 22 Pelkonen AS, Nikander K, Turpeinen M. Reproducibility of home spirometry in children with newly diagnosed asthma. *Pediatr Pulmonol* 2000; 29: 34–38.
- 23 Mortimer KM, Fallot A, Balmes JR, *et al.* Evaluating the use of a portable spirometer in a study of pediatric asthma. *Chest* 2003; 123: 1899–1907.
- 24 Reddel HK, Taylor DR, Bateman ED, *et al.* An official American Thoracic Society/European Respiratory Society statement: asthma control and exacerbations: standardizing endpoints for clinical asthma trials and clinical practice. *Am J Respir Crit Care Med* 2009; 180: 59–99.