

Impact of a Short Early Therapeutic Education Program on the Quality of Life of Asthmatic Children and Their Families

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Summary. Objectives: Few studies have been made on the impact of therapeutic education (TE) on the quality of life (QOL) of asthmatic primary-school aged children. We attempted to assess the beneficial effects on the QOL of children and their parents of a short TE program initiated immediately after the first consultation with a pediatric pulmonologist. Methods: The QOL of 31 families of asthmatic children (aged 5–11) was measured before and 3 months after a short and early programme of TE by the French version of the Pictured Child's Quality of Life Self Questionnaire (AUQUEI, *AUTOquestionnaire Qualité de vie Enfant Imagé*) for the children, and by the Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ) for the parents. The other criteria studied were asthma management, school and workplace absenteeism and functional respiratory parameters. Results: TE did not significantly alter the AUQUEI score ($P=0.67$). No change was observed in the different areas studied: autonomy ($P=0.97$), leisure activities ($P=0.64$), functions ($P=0.88$), and social relations ($P=0.51$). In contrast, the PACQLQ score considerably improved after TE ($P<0.001$), as evidenced by reduced activity limitations ($P<0.001$) and improved emotional functioning of parents ($P<0.001$). These results were accompanied by a significant improvement in asthma management, with, in particular, a major decrease in the use of medication ($P<0.001$) and the number of unscheduled medical consultations ($P<0.001$) and visits to the emergency department ($P=0.02$); a decrease in school absenteeism ($P=0.009$); and an improvement in forced expiratory volume in 1 sec (FEV_1) ($P=0.05$). Conclusions: Our TE program had rapid and beneficial effects on numerous objective and subjective parameters, thereby contributing to the well-being of the families and probably to a subsequent decrease in the overall cost of asthma management. *Pediatr Pulmonol.* © 2014 Wiley Periodicals, Inc.

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INTRODUCTION

Asthma is the most common chronic disease in children.^{1,2} In industrialized countries, it leads to considerable morbi-mortality and economic costs and is a major public health problem.^{3–5} It has been shown that chronic diseases have significant effects on individual and family quality of life (QOL), which is influenced in a complex manner by physical health, psychological state, degree of independence and social and environmental factors.^{6–8} Pediatric studies have shown that asthmatic children receive insufficient treatment despite frequent day- and night-time symptoms, regular, but avoidable, school absenteeism, repeated medical consultations and emergency admissions to hospital.^{9,10} Therapeutic education (TE) is now considered as an integral part of asthma management.⁵ The aim of TE is to help children and parents to understand the disease and its treatments and to achieve greater individual autonomy.^{11,12} Various

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studies have already shown that TE reduces the number of night-time episodes of asthma, hospital stays, admissions to the emergency department and unscheduled consultations, and can also decrease school and workplace absenteeism.^{5,13–16} It is also likely that TE programs are able to reduce morbi-mortality and asthma-related economic costs. However, opinions differ on the effects of TE programs on the QOL of asthmatic children.^{5,17–19} Most studies have been made on adolescent and pre-adolescent patients or on infants, but few on primary-school aged children. In 80% of cases the first symptoms of asthma occur before the age of 6 and in 95% of cases before the age of 9. Nevertheless, the QOL of this age group can be readily assessed.^{6,20,21} Cochrane meta-analysis shows the need for performing further prospective studies that incorporate an assessment of QOL in the impact of TE programs on the QOL of asthmatic children of intermediate age as a complement to the investigation of clinical and physiological factors.⁵ Given the great heterogeneity of this patient population, it would also be necessary to study in greater detail how TE programs are implemented, with particular attention to their duration, intensity and content.

For reasons of feasibility, TE programs in French university teaching hospitals predominantly involve asthmatic children for whom treatments have been unsuccessful. As a result, there is little documented information on the effect of these programs when they are implemented shortly after the diagnosis of asthma. The present study describes a short TE program begun at an early stage of the disease that formed part of a clinical assessment aimed at improving our professional practices. The main objective was to measure the impact of the program on the QOL of asthmatic primary-school aged children seen for the first time in consultation with a pediatric pulmonologist. The secondary objectives were to assess the effects of the program on the QOL of parents, asthma management, school and workplace absenteeism and parameters of functional respiratory tests (FRT).

MATERIALS AND METHODS

Type of Study

It was a prospective, monocentric, before-and-after, interventional study in which each family was its own control.

Population Involved

Those taking part were the families of asthmatic children attending primary-school (5–11 years old) who had been referred for a first consultation in the pediatric respiratory department, irrespective of the severity of the disease. All participants were recruited at the university teaching hospital of Clermont-Ferrand (France) between

November 2011 and February 2012. Exclusion criteria was a past enrollment in a TE or asthma education program, a chronic disease in addition to asthma (except those within the atopic spectrum of disorders such as food and respiratory allergies and atopic dermatitis), poor understanding of written or spoken French and absence at any one of the three phases of the TE program.

Data Collection

On inclusion, a record was made of the patients' general and socio-demographic characteristics and disease background (age, gender, anthropometric data, atopic status, passive smoking, date of diagnosis of asthma, anti-asthma treatments). At the first consultation with the pediatric pulmonologist (M_0 , before TE) and during the follow-up consultation (second consultation with the pediatric pulmonologist), 4 months after inclusion (M_4 , after TE), the following information was assembled in a specific individual file.

- (1) QOL of the children, as assessed by the Pictured Child's Quality of Life Self Questionnaire (AUQUEI, *AUtoquestionnaire QUalité de vie Enfant Imagé*)
- (2) QOL of the accompanying parent, as assessed by the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ)
- (3) Asthma management, as assessed by:
 - Childhood Asthma Control Test (C-ACT)
 - Type and frequency of attacks, frequency of use of short-acting bronchodilators and oral corticosteroids, number of unscheduled medical consultations, admissions to the pediatric emergency department and hospital stays in the previous 3 months, in accordance with Global INitiative for Asthma (GINA) guidelines (*GINA 2009*)²²
- (4) School absenteeism (in days), in the previous 3 months
- (5) Workplace absenteeism (in days) of the parents, in the previous 3 months
- (6) Results of functional respiratory tests (FRT, spirometry and plethysmography): forced expiratory volume in one second (FEV_1), peak expiratory flow between 25% and 75% (PEF 25–75) of the forced vital capacity (FVC), residual volume (RV) and pulmonary resistance (R_{int} , measured by flow interruption).

Collecting the data took about 30 min per family.

QOL of the Child

The pictured Child's Quality of Life Self Questionnaire has been translated into French (AUQUEI). AUQUEI is a self-assessment, non-specific questionnaire for asthmatic children aged between 4 and 12.^{23,24} It is made up of 32 separate closed questions. Each question is accompanied

by four facial expressions showing different emotional states to be rated on a scale of 0–3: “not at all pleased” (0 points), “not pleased” (1 point), “pleased” (2 points) and “very pleased” (3 points). The highest raw score is 96 points. AUQUEI explores four areas: leisure activities (3 questions, total of 9 points), family and social environment (5 questions, total of 15 points), functions (sleep, diet, 5 questions, total of 15 points) and autonomy (5 questions, total of 15 points). The use of pictograms in the assessment of QOL is a validated practice.²⁵ AUQUEI has been standardized and its psychometric characteristics have been verified (acceptability, internal consistency, reliability, and sensitivity).²³ It has already been used in various chronic diseases other than asthma.^{6,26–29} The interpretation of the answers takes into account the overall score and the accumulated score of the questions in each of the four areas. An overall score lower than 48 is generally considered to indicate impaired QOL.³⁰

QOL of the Accompanying Parent

The PACQLQ questionnaire, which is specific to asthmatic children, comprises 13 multiple-choice questions on the impact of the disease in the previous week. Each question has responses rated on a scale from 1 to 7 in ascending order of QOL satisfaction. Two areas come under study: activity limitations (4 questions) and emotional functioning (9 questions). The PACQLQ has been standardized in French and has shown its reliability in assessing very small changes over time. The interpretation of the answers takes into account the overall score and the respective average scores of the two areas studied.²¹

Asthma Management

The C-ACT has been validated in French and yields a clinical score that assesses the management of asthma over the previous month in children older than 4 years. It comprises 7 questions with answers rated in ascending order, 4 questions addressed to the child (rated from 0 to 3), and 3 to the parents (rated from 0 to 5). The maximum score is therefore 27. A score lower than 19 is suggestive of a poor management of the disease. The C-ACT score is closely correlated with the clinical, functional and biological factors of asthma management.³¹ The C-ACT score combined with the GINA criteria gives the clearest indication of how well the asthma is being managed.^{32,33}

TE Program

The TE program used in this study was granted approval in December 2010 by the French National Agency for Health Accreditation and Evaluation (ANAES). The entire program was carried out in the

Clermont-Ferrand teaching hospital and was divided into three phases. At the first consultation, the pediatric pulmonologist gave the child and the accompanying parent a general explanation of the disease and how it is treated, and explained and gave them a Written Action Plan (WAP) to be carried out in the event of an asthma attack at home (estimated time taken: 30 min) (Fig. 1).³⁴ The second phase, comprised an individual educational diagnosis and took place on the same day in the form of an interview between the child and the accompanying parent and a doctor with TE program experience (estimated time taken: 30 min). The third phase, scheduled a month later (M₁), consisted of a collective session lasting 2 h 30 min conducted by two doctors, at least one of whom had experience in leading a TE program (no more than four families per session). The topics dealt with were the pathophysiology of asthma, the symptoms of the disease, the triggering factors, the prodromal and clinical signs of an attack and the treatments (for the attack and disease-modifying therapy). The children and parents were asked standard questions and the answers were corrected interactively on the basis of the individual educational diagnosis. These activities were organized like games and

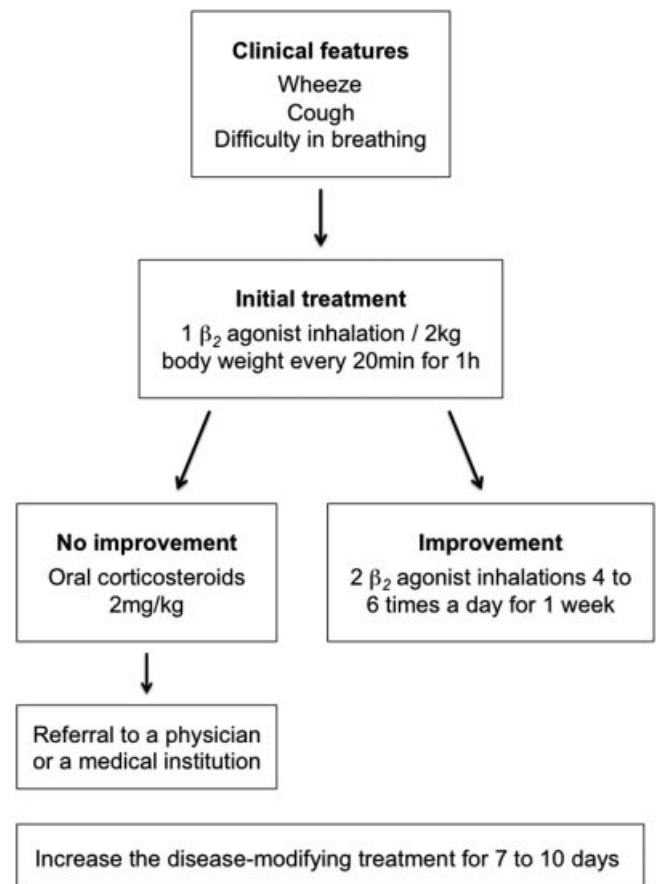


Fig. 1. Details of individual Written Action Plan (WAP) in case of asthma crisis following French guidelines.

all taking part were encouraged to handle the different drugs and devices used in treatment (real or dummy). The concrete short-term aims were to understand and manage the symptoms of the disease, comply better with treatment, be able to recognize the first signs of an attack and quickly start appropriate treatment.

Organizational Framework of the Study

The general structural outline of the study is given in Figure 2.

Statistical Considerations

Sample Size Estimation

According to the literature, data concerning quality of life indicated a mean of AUQUEI score of 2.09 (standard-deviation (SD) equals 0.28, total score between 0 and 3) for a global population of children.²⁴ Also, considering a sample size estimation based on a paired *t*-test, less than 10 subjects were needed to highlight a difference of 0.5 for a two-sided type I error of 5%, a power of 95% and a correlation coefficient of 0 (worst perspective in paired situation). Finally, in order to study differences for each of the four dimensions of the AUQUEI scale (inflation of type I error), the inclusion of more than 30 patients was expected.

Statistical Analysis

Stata software, version 12 (StataCorp, College Station, TX) was used for statistical analysis. The tests were two-

sided, with a type I error set at $\alpha = 0.05$. Baseline characteristics were expressed as the mean $\pm$ SD or the median [interquartile range] for continuous data (assumption of normality assessed by using the Shapiro–Wilk test) and as the number of patients and associated percentages for categorical parameters. Paired Student's *t*-test or Wilcoxon test was used to study evolution in the quality of life of children and their parents. The secondary quantitative endpoints were analyzed in the same way. The “before–after” comparisons for categorical variables were performed with the Stuart–Maxwell test.

Multivariate analysis (linear regression) concerning age, gender, passive smoking, atopic profile, prior diagnosis and previous anti-asthma treatment were performed to ensure that these factors were not associated with the AUQUEI score (neither the variation nor the “before–program”). For analysis of the “after–program” AUQUEI score as a dependent variable, the “before–program” AUQUEI score was fixed as a covariate (data not shown). However, because of the sample size, these results should be treated with caution.

Legislative Framework

Informed consent was required from the children and parents to take part in the program. The study was approved by the French ethics committee. It was conducted in compliance with the recommendations for good clinical practice and the Declaration of Helsinki. The data were rendered anonymous in accordance with

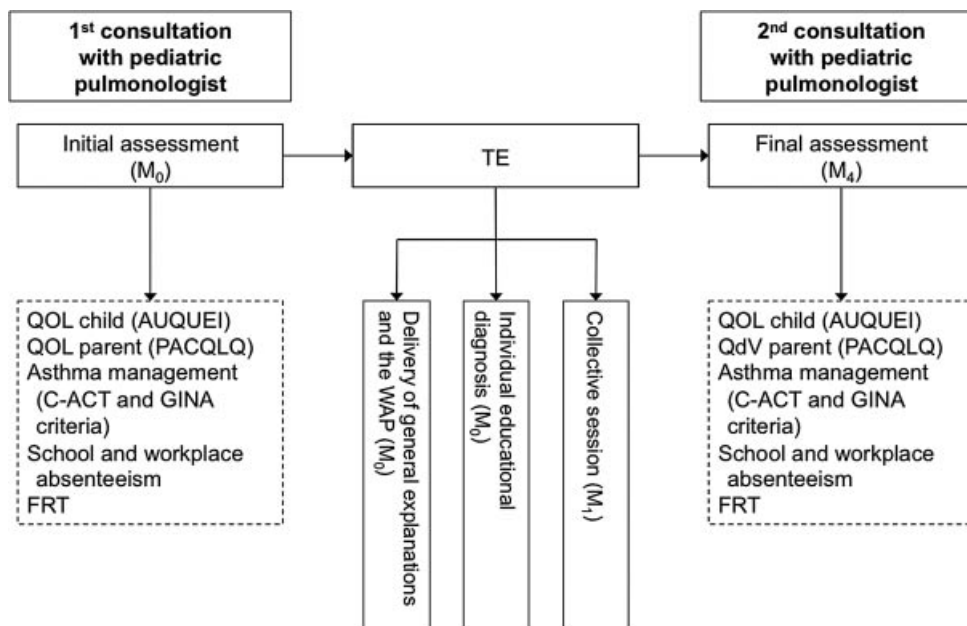


Fig. 2. Organizational framework of the study. AUQUEI, Autoquestionnaire Qualité de vie Enfant Imagé (pictured child's quality of life self questionnaire); FRT, functional respiratory test; GINA, Global initiative for asthma; PACQLQ, paediatric asthma caregiver's quality of life questionnaire; QOL, quality of life; TE, therapeutic education; WAP, written action plan.

regulations of the CNIL (French National Agency Regulating Data Protection).

RESULTS

Of the 37 families that fulfilled the inclusion criteria, 35 were recruited for the study. Four families were later excluded because of an absence at one of the phases of the TE program. Hence, the statistical analysis at M_0 and M_4 concerned 31 families (Fig. 3), except for use of medication, workplace absenteeism, QOL of parents and parameters of FRT ($n = 30$) because some questionnaires were not fully completed.

Socio-Demographic Characteristics of the Patient Population

The mean age of the children on inclusion was 8.1 ± 1.5 years. Twenty children (64.5%) were aged between 5 and 8, and 11 (35.5%) were older than 8. There were more boys ($n = 22$; 71%) than girls. Fifteen children (48.4%) had a history of allergy. Thirteen (41.9%) were regularly exposed to passive smoking. A diagnosis of asthma had already been made 6 months before inclusion in 17 patients (54.8%). Fourteen patients (45.2%) had already received a disease-modifying treatment. No significant difference was found between the studied population ($n = 31$) and the patients who were excluded ($n = 6$).

QOL of the Children

On inclusion, the children had an AUQUEI score of 71.3 ± 9.1 . They all had a score greater than 48. No significant difference was found after the TE program,

neither in the overall score, which was 71.4 ± 9.1 at M_0 and 71.3 ± 9.3 at M_4 ($P = 0.67$), nor in the four separately studied areas: autonomy (9.2 ± 2.9 at M_0 ; 9.1 ± 2.9 at M_4 ; $P = 0.97$), leisure activities (8.5 ± 0.8 at M_0 ; 8.6 ± 0.5 at M_4 ; $P = 0.64$), functions (11.1 ± 2.6 at M_0 ; 11.0 ± 2.5 at M_4 ; $P = 0.88$), and family environment and social relations (12.1 ± 2.3 at M_0 ; 12.4 ± 2.2 at M_4 ; $P = 0.51$). These results are shown in Figure 4.

QOL of the Parents

The overall PACQLQ score considerably improved, from 5.5 ± 1.1 at M_0 to 6.3 ± 0.9 at M_4 ($P < 0.001$; $n = 30$). An improvement in the scores for the two separately studied areas was also observed after the TE program: activity limitations (5.8 ± 1.1 at M_0 ; 6.3 ± 0.9 at M_4 ; $P < 0.001$) and emotional functioning (5.4 ± 1.3 at M_0 ; 6.3 ± 1.0 at M_4 ; $P < 0.001$). These results are given in Figure 5. Gender, passive smoking, atopic profile, prior diagnosis, and previous anti-asthma treatment were not associated with the PACQLQ score, neither before nor after the TE program. For age, in contrast, although the difference between the two groups (5–8 years old and >8 years old) were not significant, the QOL of the parents of the younger children (age range of 5–8) showed greater improvement (increase in the PACQLQ score of 17%, $n = 19$) than that of the parents of the older children (>8 years old) (increase in the PACQLQ score of 9%, $n = 11$).

Management and Severity of the Asthma

Asthma management improved considerably after the TE program. The results are given in Table 1 ($n = 30$).

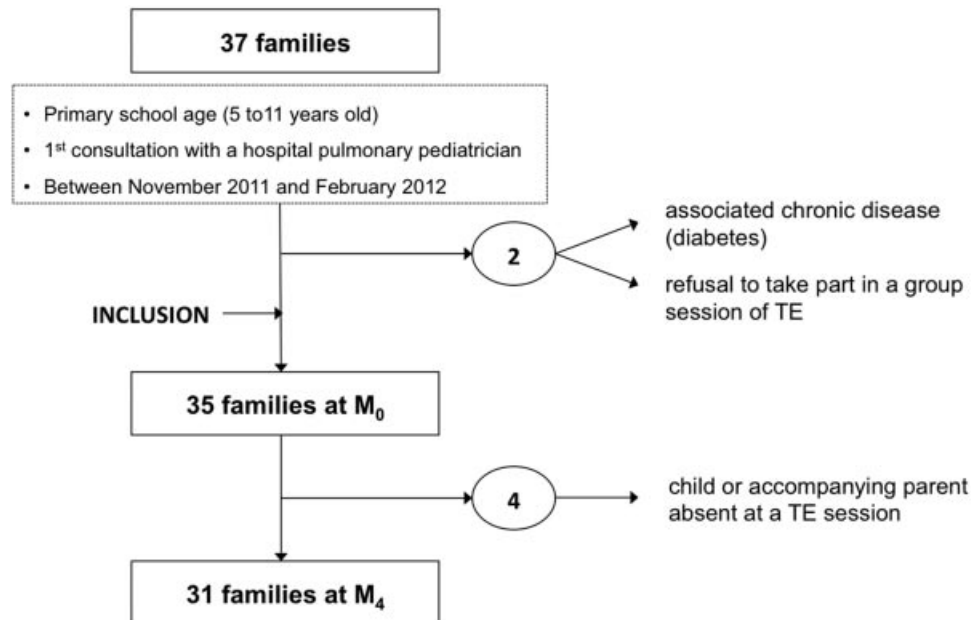


Fig. 3. Flow chart. TE, therapeutic education.

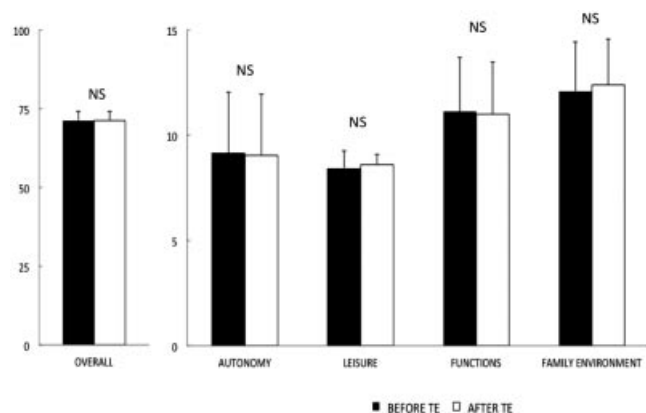


Fig. 4. Results of the AUQUEI questionnaire before and after TE for the overall score and for each score in the four separate areas (autonomy, leisure activities, functions and family environment) (n = 31). AUQUEI, AUtoquestionnaire QUalité de vie Enfant Imagé (pictured child's quality of life self questionnaire); TE, therapeutic education.

Three children (9.7%) had been admitted to hospital during the 3 months before M_0 whereas none required admission during the 3 months before re-assessment at M_4 ($P = 0.08$).

No child was suffering from severe persistent asthma, neither on inclusion nor at the end of the study. Moderate persistent asthma was seen in 35% of the patients (n = 11) before the TE program but only in 6.5% (n = 2) after the program. Hence, the rate of intermittent asthma increased from 29% (n = 9) before the TE program to 55% (n = 17) thereafter (Table 2). These results are reflective of a decrease in the severity of the disease ($P = 0.001$).

School and Workplace Absenteeism

School absenteeism in the 3 months before re-assessment decreased significantly (0.97 ± 1.85 days

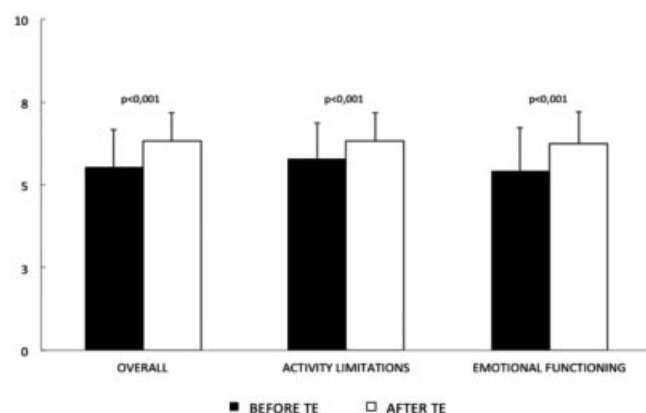


Fig. 5. Results of the PACQLQ questionnaire before and after TE for the overall score and for each score in the two separate areas (activity limitations and emotional functioning) (n = 30). PACQLQ, paediatric asthma caregiver's quality of life questionnaire; TE, therapeutic education.

before the TE program; 0.06 ± 0.25 days after the TE program, $P = 0.009$) (n = 31). There was also a trend toward a decrease in workplace absenteeism (0.27 ± 0.98 days before the TE program; 0.0 ± 0.0 days after the TE program, $P = 0.08$) (n = 30).

FRT

A significant improvement in FEV_1 was observed after the TE program ($97.0 \pm 16.9\%$ of the predicted theoretical value for age, gender and weight before the TE program versus $103.1 \pm 12.1\%$ of the predicted theoretical value after the TE program, $P = 0.05$), in combination with a trend toward an improvement in PEF 25–75 ($93.4 \pm 34.2\%$ of the predicted theoretical value before the TE program versus $106.4 \pm 27.9\%$ of the predicted theoretical value after the TE program, $P = 0.07$) (n = 30). The other functional parameters were not significantly altered.

DISCUSSION

The TE program implemented in this study did not modify the QOL of the asthmatic patients but did improve that of their parents, along with asthma management, school and workplace absenteeism, use of medication, emergency hospital visits and pulmonary function. The socio-demographic characteristics of the patients studied were comparable to those of asthmatic children coming to a first consultation with a pediatric pulmonologist at the university teaching hospital of Clermont-Ferrand. The results regarding the QOL of our patients are consistent with some but not all of those of other studies, certain of which report improved QOL following a TE program.^{5,18,19,35}

The sample size was not a limitation of the main objective of this study since it was calculated to evidence a minor statistical difference of 0.2 points per question. The AUQUEI score before and after the TE program was the same (2.23 ± 0.28 on a scale of 3) and was higher than the estimated score (2.09 ± 0.28) for a similar sample size reported elsewhere. A larger sample size would not have yielded a difference in this finding. In addition, the statistical power was sufficient to assess the QOL of the accompanying parent (PACQLQ questionnaire): it was greater than 95% to show a difference between M_0 and M_4 (respectively 5.5 ± 1.1 and 6.3 ± 0.9) for a two-sided type I error of 5% on the basis of an inclusion total of 31 patients. Data collection was thorough. The before-and-after methodology was chosen in light of national ethical recommendations, which insist that information and education should be “minimal.” We would not have been granted approval by national ethics committees to create a randomized control group because the notion of minimal information is open to interpretation and the doctor would have been required to carry out therapeutic

TABLE 1—Results of the C-ACT and of Asthma Management Parameters Before and After TE

	Before TE	After TE	P-value
C-ACT	20.8 ± 3.7	22 ± 3.4	0.03*
Number of times β mimetic drug taken	17.7 ± 30.4	5.0 ± 11.2	<0.001***
Number of times oral corticosteroids taken	1.3 ± 2.0	0.4 ± 0.9	0.04*
Number of medical consultations	1.1 ± 1.4	0.2 ± 0.5	<0.001***
Number of visits to emergency department	0.2 ± 0.5	0.0 ± 0.0	0.02*

C-ACT, childhood asthma control test; TE, therapeutic education.

The C-ACT assessed asthma management over the month before completion of the questionnaire. The other parameters concerned the three previous months. These results are expressed as mean $\pm$ standard-deviations (SD).

* $P < 0.05$.

*** $P < 0.001$.

patient education and to draw up a WAP for asthma attack. In our patient population, the overall and area-specific scores (in particular the higher score for leisure activities and the lower one for autonomy) are in agreement with those in the literature for the general population of the same age.²³ They are also consistent with the short lapse of time between the onset of the disease and the beginning of TE program (half of the children in our study were diagnosed in the 6 months before inclusion), the severity of the disease (65% were suffering from intermittent or mild persistent asthma but none had severe persistent asthma), disease management (mean C-ACT score on inclusion was higher than 19) and respiratory function (the FRT parameters at outset were within the normal range). Uncontrolled asthma is a recognized factor in impaired QOL.^{36,37} The decision to include children referred for a first consultation in the pediatric respiratory department was in line with our aim of assessing the impact of a TE program as early as possible in the course of the disease. The inclusion period and the follow-up at 4 months were kept short so as to avoid seasonal bias, which could have modified both the objective (current-life conditions, functional parameters) and subjective (satisfaction, happiness, well-being) factors governing QOL. It was decided not to have a long follow-up period because it would have increased the difficulty of interpreting the data, which in the assessment of the QOL include dynamic components such as age, family and social

context. It would also have increased the bias accruing from the before-and-after nature of the study, in particular the risk of incomplete data. The AUQUEI has the major advantage of being a self-report questionnaire, which is widely recognized to be more reliable in assessing QOL.^{38,39} A specific assessment scale may have yielded more accurate results, but unfortunately no specific self-assessment scale for children aged 5 years and upwards has been validated in French.³⁹ It was not possible to use the Paediatric Asthma Quality of Life Questionnaire (PAQLQ), since the minimum age required for this questionnaire is 7 years old.³⁵ Discrepant results on the impact of TE programs on the QOL of children have been reported with both specific and non-specific assessment scales.^{5,18,19,35}

In our study, no change was observed in the QOL of the children but significant improvement was seen in that of their parents. The overall score on the PACQLQ scale for parents was comparable on inclusion to that reported by Dolinar et al. in a study of parents of asthmatic children of the same age.¹⁷ In their study, which also tested a program consisting of a single TE session and a short follow-up period of 3 months, no difference in the parents' QOL was observed. In contrast, certain studies have evidenced an improvement in the QOL of parents following a TE program, in particular in the area of activity limitations.³⁵ In our study, a major improvement in the QOL of parents was seen in both activity limitations and emotional functioning. One possible explanation of the discrepancy between the positive outcome of the parents and the outcome of the children could be the feeling of empowerment imparted to the adults by the TE program. A further explanation could be the use of the WAP, which greatly contributed to the parent's well-being and had a beneficial effect on their QOL. In addition, the improved score for activity limitations and emotional functioning suggest that the TE program helped decreased parental anxiety. Overall, the improvement in the parents' QOL was greater in the youngest children's parents. The absence of any significant result of the TE program on the

TABLE 2—Severity of Asthma Before and After TE

Level of asthma severity	Before TE n (%)	After TE n (%)
Intermittent	9 (29%)	17 (54.8%)
Mild persistent	11 (35.5%)	12 (38.7%)
Moderate persistent	11 (35.5%)	2 (6.5%)
Severe persistent	0 (0%)	0 (0%)

TE, therapeutic education.

These results are expressed as numbers and percentages of patients.
 $P = 0.01$.

children's behavior may have been due in part to their inability to assess improvement in their physical and psychological status. However, this finding needs to be confirmed on the basis of a larger study sample. The improved emotional functioning of the parents, which was probably related to a more reassured view of their child's condition, could also help reduce the use of non-essential medication.

Our study confirms the beneficial effects of TE programs on asthma management, school and workplace absenteeism, use of medication, emergency care and pulmonary function widely reported elsewhere.^{5,16,17,40} Although there are conflicting reports in the literature on whether TE programs improve the parameters of FRT, the significant improvement in FEV₁ seen in our study, despite the initial values being within the normal range, is an important factor since it is reflective of improved flow in the major airways.¹⁸

No external factor, such as local or national public health programs or other interventions, influenced the results of our study. The improvements prospectively observed resulted from a program divided into different phases, including a single collective TE session following on from a medical consultation, whereas most studies are based on programs with multiple TE sessions.⁴⁰ Our program was greatly appreciated by the families, who were unanimous in expressing their satisfaction. It had a beneficial effect on a number of objective and subjective parameters, is easy to implement and is accessible to most patients receiving care in a university hospital.

Although it did not modify the QOL of asthmatic primary-school aged children, the TE program carried out in this study did improve that of their parents. It also brought about improvements in asthma management, school absenteeism, use of medication, emergency care and pulmonary function, thereby contributing not only to the families' well-being but also, in all likelihood, to a decrease in the overall economic costs of treating the condition. This type of program, short but implemented very early on in the course of the disease, gave rapid and encouraging results, in particular for the public health services since it can be easily adopted for a large proportion of patients. We think it is important to encourage the systematic use of this type of program but uncertainty remains about how long its effects will prevail. This is a major question that needs to be addressed in order to develop appropriate long-term strategies.

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