ORIGINAL RESEARCH

Application and implementation of the GINA asthma guidelines by specialist and primary care physicians: a longitudinal follow-up study on 264 children

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Abstract

Aims: To implement GINA guidelines and to assess their impact on the management of childhood asthma.

Methods: A working group of primary care physicians (PCPs) and specialists developed a GINA-based clinical pathway. We then monitored the impact on 385 children (aged 0-15 years) referred to the respiratory outpatients clinic at the University Children's Hospital, Brescia, Italy by 179 PCPs between September 2003 and July 2005.

Results: Mean follow-up for 264 children with complete datasets was 10 months. Guidelines were followed by 94.6% of the PCPs. 98.6% of children learned to manage exacerbations. Half of the patients with persistent symptoms became intermittently symptomatic. Maintenance treatment was suspended in 47.2%, reduced in 27.6%, and increased in 4.9%. Asthma severity diminished ($p < 0.0001$) and requirement for medication for exacerbations was significantly reduced ($p < 0.0001$).

Conclusions: Regular specialist visits, a website, and a written management plan shared by all those involved, led to clinical improvements as well as a reduction in, and more efficient use of, asthma medication.

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Introduction

In 1993 the American National Heart Lung and Blood Institute (NHLBI), in cooperation with the World Health Organisation, promoted the "World Project for the Treatment and Prevention of Asthma" and the Global Initiative for Asthma (GINA). The aim was to develop a global plan for treating asthma and to spread the use of the guidelines, adapting them to the conditions in each country.^{1,2}

Recent data have shown that worldwide mortality for asthma has become stable or has even dropped in several countries.^{3,4} A larger number of patients are being identified and treated, and the cost to public health services seems to be lower where GINA guidelines have been applied correctly.^{5,6}

However, differences in public health services and the variable availability of treatment options in different countries imply that the guidelines have to be adapted locally.^{7,8} Several studies emphasise how important it is to apply international guidelines at the local level and to ensure close cooperation between primary and secondary care providers in the management of chronic diseases such as asthma.⁹⁻¹²

In combination with a group of 19 interested primary care physicians we designed, constructed, applied and implemented a diagnostic and therapeutic protocol (a "clinical pathway") based on the GINA guidelines with the aim of ensuring appropriate diagnosis, classification and treatment of children with asthma.

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Methods

Study design, patient eligibility

Sixty primary care physicians out of 113 working in the territory of Brescia were contacted by personalised mailing and invited to participate in a working group on GINA guidelines under the auspices of the local health authority and the Italian Society for Paediatric Respiratory Diseases (SIMRI). We organised six joint meetings focused on asthma diagnosis, therapy and communication, with educational material, to which primary care physicians were invited to bring cases they perceived as being difficult. The guidelines and educational material – together with a rapid access specialist service for confirmation and advice, if necessary, on patient management – were then offered to all primary care physicians throughout the local health authority.

In order to monitor the impact of applying and implementing the GINA paediatric asthma guidelines, we evaluated 416 consecutive children referred to our centre for respiratory symptoms suggestive for asthma (Visit 1). To be eligible, patients had to have a history of asthma-like symptoms (i.e. wheezing, cough, shortness of breath, chest tightness or a documented response to inhaled bronchodilators), or a diagnosis of asthma made by a primary care physician. A total of 179 primary care physicians participated. In all cases, the diagnosis of asthma had to be confirmed by the specialist, using spirometry testing where applicable. Patients who did not attend for specialist Visit 2 – at least three months after Visit 1 – were excluded from the analysis.

The specialist evaluation: the clinical pathway (diagnostic therapeutic protocol)

The clinical pathway was developed and adopted to facilitate communication and sharing of the proposed diagnostic and treatment plan between the specialist and the primary care physician.

Visit 1

The report at the first visit covered: family history of atopy, asthma, allergic rhinitis and smoking habit (first- and second-degree relatives); neonatal and perinatal history (focusing on prematurity, allergies or airway diseases); history of airway diseases and asthma symptoms (dry or productive cough, resting or exercise-induced wheezing, bronchospasm, waking at night due to coughing, chest tightness, rhinorrhea, nasal obstruction, conjunctivitis, atopic dermatitis). In addition, we recorded: treatment provided for attacks of bronchospasm and their efficacy; past or present maintenance treatment (drug and dosage, frequency of administration and any adverse effects); pulse oximetry; utilisation of emergency services; and/or hospitalisation. Follow-up visits were scheduled at 2-monthly intervals with the patient's primary care physician.

Patients and their families also received information and

training on the management of acute attacks and on maintenance treatment, including the proper use of inhaler devices for drug administration and how to avoid asthma triggers. Printed information sheets and diary cards, developed in cooperation with a clinical teacher and specific for the patient's age, were handed out to the family.¹³

Visit 2

A second specialist visit was felt to be crucial in order to assess compliance and symptom control. Any further investigation felt to be necessary – such as allergy testing or repeat lung function tests – was performed at this visit. This visit was used to reassess the patient, adjust the severity classification, and to modify treatment as necessary. Patients' compliance with the protocol use of medication and inhaler devices was ascertained, and the primary care physician's acceptance of this treatment was recorded.

Lung function measurement

Spirometry was performed by means of a bell spirometer (manufactured by Biomedin Baires, Padua, Italy) according to ATS guidelines.¹⁴

Skin prick tests

Skin prick tests were performed for the most common allergens, such as dust mite, *Alternaria*, grass, tree, ragweed, cat, dog, and others as indicated (manufactured by Lofarma, Milan, Italy).

Statistical analysis

Data was collected in a database and analysed using descriptive and inferential statistical methods using STAT version 8.0. Student's t-test and Wilcoxon's test were used as appropriate to compare the symptoms and diagnostic variables between baseline and the end of follow-up.

Results

Patients

A total of 416 consecutive patients were referred to our specialist outpatient clinic, and of these, 31 were excluded who did not have asthma. The study group thus consisted of 385 patients (241 males [62.6%] and 144 females [37.4%]) aged from 0 to 15 years. The patients' mean age was 6 years. In 264/385 patients, the follow-up lasted at least three months (mean 10, max 34 months), with the mean number of visits being 4.8, and the mean interval between visits being seven weeks. Among those who did not complete at least three months of follow-up a higher percentage had asthma classified as 'intermittent' (63.2% vs 39.3%) while age distribution was no different from the study group with complete data.

Diagnostic and therapeutic protocol: concordance between primary and secondary health care providers

Concordance of asthma diagnosis, as defined by the GINA guidelines, between the primary care physicians and the

specialist at the first visit was 67.5% (260/385 concordant diagnoses). If the primary care physician's diagnosis was not available, the diagnosis of asthma was deduced by the treatment which had been prescribed. In 70 cases asthma was not recognised by the primary care physician; thus, asthma was under-diagnosed in 18.18% of our series, with recurrent bronchitis being the most common inappropriate diagnosis. This tendency to under-estimate asthma by the primary care physicians was confirmed by the fact that 89 patients who had been classified as 'intermittent' or 'exercise-induced' asthma were reclassified by the specialist as having 'persistent' asthma. Concordance in the classification of symptoms and severity (intermittent, persistent, and exercise-induced asthma) was 83.6%, 56.2% and 57.1%, respectively.

At Visit 1, the concordance between the primary care physician and the specialist in relation to long-term treatment with anti-inflammatory medication was 63.4% for the type of drug and 37.4% for the dosage in those patients classified by both physicians as having 'persistent' asthma. However, for those patients classified as having 'persistent' asthma by their primary care physician independent of the specialist's evaluation, the choice of maintenance treatment (drug and dosage) prescribed by the referring physician was confirmed by the specialist in only 21% of patients.

The consistency between the type of medication prescribed by primary and specialist physician for treating acute exacerbations, based on the GINA guidelines, was 31.7% at the first visit (122/385), showing a strong tendency to over-treatment by the primary care physicians.

The protocol was well accepted by the primary care physicians: 94.6% of them implemented the program proposed by the specialist. At Visit 2, 87% and 76.8% respectively of the primary care physicians had prescribed the drug and dose of controller medication as recommended by the specialist.

Asthma exacerbation management

Prior to Visit 1, antibiotics had been administered to 29.4% of children, oral steroids to 23.5%, and inhaled beta2-agonists alone, or in association with inhaled steroids, to 12.4% and 26.3% of cases, respectively. At the end of follow-up, as assessed by self reporting, interview, and simulation, the patients and/or their families were capable of managing an asthma exacerbation following the guidelines in 98.6% of cases.

In terms of the devices used to administer reliever medication for an asthma attack, data collected at the first visit showed that 8.6% of the children used a spray aerosol without a spacer to administer the medication, 63.5% used a nebulized aerosol and 27.8% used a spray aerosol with a spacer. At Visit 2, all patients reported using a device to administer their medication and the proportions were reversed for those using a nebulized aerosol alone (30.3%) or a spray aerosol with a spacer (69.7%). At the last follow-up visit, the percentage of patients using a nebulized aerosol and a spray aerosol with a spacer was even higher: 24.0% and 75.9%, respectively. When patients were divided by age, we found that at the first visit patients aged less than 2 years were predominantly treated with aerosol therapy (83.3%), which remained the most common delivery system for this

Figure 1. Variation in the frequency of asthma-related symptoms (wheezing, cough, shortness of breath, chest tightness) divided by severity (intermittent, left; persistent, right) from the first visit to the last follow-up available for each patient.

Figure 2. Variation in the classification of asthma severity from the first visit to the last follow-up available for each patient.

age group even at the end of follow-up (68.3%). In older children the use of aerosol devices decreased over time; in the 3-6 year olds from 71.3 to 29.2% and in the 7-11 year olds from 47.4 to 2.6%. The lowest proportion of aerosol use was seen in those over 12 years, where the percentage dropped from 46.3 to 1.9%.

The application of the GINA guidelines also led to a consistent reduction in the frequency of use of exacerbation medications ($z=12.610$, $p<0.0001$).

Variation in symptoms and disease severity

We found a reduction in the frequency of symptoms during follow-up ($t=6.9936$, $p<0.0001$) and consequently a change in disease classification after implementation of the GINA guideline. Overall, the number of patients suffering from persistent asthma dropped from 63.4% at the first visit to 37.3% at the end of follow-up (see Figure 1). Patients with intermittent asthma consequently rose from 36.6% to 62.6% (Figure 2). Student's t-test and Wilcoxon's test were consistent in demonstrating that correct asthma management permitted a reclassification and a step-down in asthma severity ($t=7.4302$, $p<0.0001$; $z=6.550$, $p<0.0001$).

Variation in controller treatment

We considered the 163 patients classified as having persistent asthma by the specialist at the first visit who were advised to adopt maintenance treatment. In 47.2% of patients the treatment was suspended at the end of the follow-up, in 27.6% treatment was reduced, in 20.2% the treatment remained unchanged, and in 4.9% of cases it was increased (Figure 3).

Figure 3. Variation in the treatment (drug and dose of controllers) used by the patients to achieve control of asthma-related symptoms over the study period.

Hospitalisation

Prior to Visit 1, 51.6% and 89.8% of children suffering from intermittent and persistent asthma, respectively, had been hospitalised for asthma.

During the follow-up period, the rate of Emergency Room attendance by children with intermittent and persistent asthma because of asthma symptoms fell to 4.3% and 8.0%, respectively, and only 2.4% of the children with persistent asthma were hospitalised for asthma.

The hospitalisation rate was 0.23 admissions/patient/year prior to Visit 1, and 0.12 admissions/patient/year during the entire length of follow-up.

Discussion

Several guidelines have now been produced for the management of common chronic conditions such as asthma. They are regarded as useful tools, designed to aid the busy clinician, but their application to primary care needs to be assessed critically. Ideally, guidelines are part of a carefully-planned program.¹⁵

We designed this study by focussing on the interaction between the specialist and the primary care physician right from the start of the definition of the clinical pathway, in order to facilitate sharing and implementation of the guidelines in a standardised manner. A clinical pathway (diagnostic therapeutic protocol) is useful to all three participants – the patient, the specialist and the primary care physician – and this message was supported by the local health authority.^{16,17}

For some years now, a network of professionals

(physicians, nurses, school teachers, pharmacists, sports coaches), have collaborated to promote a better quality of life for asthmatic children and their families, and have provided them with a structured dedicated professional website.^{18,19} Shared protocols – but also shared clinical data for each individual patient through monitoring cards – adds security to patients and allows for better self-management. Knowing that their primary care physician is part of a larger network increases trust in the individual physician and in the system so that any contact made with the specialist is now perceived as high quality care and not as inadequacy. As a result of this process, concordance in the diagnosis of asthma between primary care physicians and specialists rose by nearly 50% during the study period. This increase was observed for all subgroups of asthma (persistent, intermittent, and exercise-induced). Even more importantly, concordance on medication to be used for maintenance therapy and for acute attacks more than doubled following implementation of the guideline. The goal of the therapeutic educational plan was to keep the symptoms under control with the minimum amount of medication. The data we present emphasise the importance of sharing such a diagnostic-therapeutic pathway between all physicians involved in the care of children with asthma, ensuring that the patient (and/or parents) is given accurate unambiguous information which can easily be followed.^{20,21}

It is essential not only to prescribe the appropriate medication but also to ensure its proper administration, thereby significantly reducing the quantity of medication needed to control symptoms²² and therefore reducing side effects and cost. This is especially important for inhaled drugs in childhood and adolescence. Although the Cochrane database shows no difference in effectiveness between the use of spacers as compared to nebulised aerosols to deliver medication for acute asthma,²³ the GINA guideline recommend spacers as the method of choice in paediatric patients – even though the Disk Inhaler or nebuliser with face mask are also acceptable. We promoted the use of the pressurised metered dose inhaler (pMDI) plus spacer, but the final decision on what system to use was left to the individual physician taking into account the patient's preferences.

The reduction in the quantity of medication and the number of doses required (for attack and maintenance) was also achieved using appropriate devices in more than 90% of patients at the end of the follow-up. Much time was spent at the first visit explaining the proper use of drugs and devices, and detailed information sheets were given for reference at home, thus reinforcing the educational process. The efficacy of this approach was underscored by a significant drop in the number of patients with persistent symptoms after being in the programme.

Correct implementation of the GINA guideline also

improved the quality of life of the patients and their families because of less or absent daytime and nocturnal symptoms, reduction of activity limitations, and normal lung function. This then permitted a reduction in severity classification in many patients and consequently a reduction in drug use.²⁴⁻²⁷

An early and accurate diagnosis is fundamental in order to choose the best available management of this frequent chronic disease of childhood. Such a diagnostic/therapeutic pathway needs to be updated regularly on the basis of new scientific information and needs the feedback of all partners interested in making the life of children with asthma less difficult.²⁸

This study reports the results of our analysis of a series of data that were collected before and after an educational intervention. The study design has important methodological weaknesses in that it is uncontrolled and has limited multivariate analysis. However, whilst additional randomised studies – with inclusion of a control group and a robust multivariate analysis – will be necessary to substantiate the conclusions deriving from this preliminary observation, we believe that our study illustrates the importance of solid educational interventions in improving the management of children with asthma.

Conclusions

Obtaining optimal and stable control of a chronic disease such as asthma demands close co-operation and ongoing communication between primary care physicians, secondary care specialists, other healthcare professionals such as nurses and pharmacists, teachers and – last but not least – patients and their families.²⁹ An integrated and structured diagnostic and therapeutic management protocol consistent with the recommendations of the GINA international guideline and supported by new technologies has been shown to reduce significantly the impact of asthma and to improve the quality of life of children, their families and participating physicians.³⁰

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Conflict of interest declaration

None declared.

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