Monitoring of Asthma Outpatients After Adapting Treatment to Meet International Guidelines

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OBJECTIVE: Poor control of asthma treated in outpatient settings has been demonstrated. The aim of this study was to perform a short intervention, readily replicable in everyday practice, to try to improve control of asthma symptoms.

PATIENTS AND METHODS: Two primary health care clinics made appointments with asthma patients to administer a questionnaire and adapt their treatment to the guidelines of the Global Initiative for Asthma. Patients also received an explanation of the disease lasting not more than 5 minutes. The protocol was repeated at a second visit 4 months later.

RESULTS: The characteristics of the 180 patients were as follows: 70% were women, 17% were smokers, 8% were illiterate, 46% had only primary education, 45% were in contact with cleaning products, and 63% had extrinsic asthma. The asthma severity was as follows: mild in 73%, moderate in 23%, and severe in 4%. Twenty-two percent had received previous explanations of the disease, 50% had a written treatment plan, 14% had a plan for exacerbations, and 54% were taking inhaled corticosteroids. The second appointment was kept by 110 (61%) of the patients, who showed differences with respect to the previous visit 4 months earlier in the percentage taking inhaled corticosteroids (78%, p < 0.001), the number of visits to the physician (Pc<0.001), visits to the physician due to exacerbations (78%, Pc<0.001), emergency visits to the outpatient clinic (Pc<0.002), and disease severity (P<0.02).

CONCLUSIONS: This minimal clinical intervention reduced the need for visits to health care centers and improved the clinical control of the disease.

La población de asmáticos ambulatorios y su control tras adaptar el tratamiento a las recomendaciones internacionales (ASMACAP I)

OBJETIVO: Los pacientes asmáticos en régimen ambulatorio muestran un deficiente control de su enfermedad. El objetivo de este estudio ha sido realizar una intervención corta, y factible de repetir en la práctica, con el fin de intentar mejorar dicho control.

PACIENTES Y MÉTODOS: Se citó a los pacientes asmáticos de 2 centros de asistencia primaria para encuestarles, adaptar el tratamiento según las recomendaciones de la GINA (Global Initiative for Asthma) y explicarles en 5 min en qué consistía la enfermedad. A los 4 meses se realizó una segunda visita repitiendo el protocolo. Se compararon los parámetros asistenciales de los 4 meses anteriores a cada visita.

RESULTADOS: De las características clínicas de los 180 pacientes destaca que un 70% eran mujeres, un 17% fumaba, un 8% eran analfabetos, un 46% únicamente tenía estudios primarios, un 45% estaba en contacto con productos de limpieza y en un 63% el asma era extrínseca. Por lo que se refiere a la gravedad del asma, en un 73% ésta era leve, en un 23%, moderada y en un 4%, grave. Un 22% había recibido explicaciones sobre su enfermedad, un 50% tenía el tratamiento por escrito, un 14% tenía un plan para las exacerbaciones y el 54% recibía corticoïdes inhalados. Los 110 (61%) que acudieron a la segunda visita mostraron diferencias, en los 4 meses previos a cada visita, en el tratamiento con corticoïdes inhalados (78%, p < 0.001) en el número de visitas a su médico (p < 0.001), en las visitas por apalancamiento a su médico (p < 0.001) y a urgencias en su ambulatorio (p < 0.002), y también en el estadio de la enfermedad (p < 0.02).

CONCLUSIONES: Esta actuación clínica mínima ha reducido la frecuentación a los centros asistenciales y ha mejorado el grado de control clínico de los pacientes.
Patients and Methods

Patients

The patient lists of 2 primary health care clinics were consulted, and consecutive patients with asthma were scheduled to have an appointment with a pulmonologist in the corresponding center in order to update their treatment. The study was approved by the ethics committee of the Hospital Universitari Vall d’Hebron, Barcelona, Spain.

Baseline Visit

A primary health care physician called 8 patients per week by telephone to arrange an appointment with 4 of them per day on 2 different days. Once in the clinic, the patients were attended by 1 of the 2 pulmonologists who participated in the study and who were not affiliated with the study centers. These specialists followed a protocol that comprised: a) questioning the patients about their profession, smoking habit, consumption of alcohol and other drugs, pets in their home, allergic manifestations other than asthma (rhinitis, conjunctivitis, eczema, urticaria), and the results of skin prick tests or determination of specific serum immunoglobulin E if 1 or both tests had been performed; b) asking the patients whether they had been given an explanation of their disease, whether they had been given a written treatment plan, and whether their disease was monitored in any other way, as well as asking them about the treatment they were actually using and assessing the degree of asthma control according to their symptoms (cough, wheezing, dyspnea, and rescue medication used), frequency of visits to the primary health care physician and the emergency services, and absence from work or school, and therefore to a greater economic burden on the health system. For example, the average total cost generated by an asthmatic patient in the district of Osma, near Barcelona, Spain, was calculated to be US $2879 per year in 1995, whereas the cost of treating a patient with severe disease was 6 times greater. The patients with poorest asthma control, representing a fourth of the population, accounted for more than half the total cost of the disease.18

Several studies have shown that those patients who follow an educational plan to inform them about asthma, have a written treatment plan, monitor their disease, and attend the clinic regularly have better disease control,2 and these findings have been confirmed in Spain by Ignacio-García et al.23 For these educational plans to be effective, the physician or nurse must dedicate a certain amount of time to them at each visit, and so their application in clinical practice is difficult. Faced with the lack of studies that show the effectiveness of these sample interventions,30 experts recommend that studies should be undertaken.31

The aim of this study was to determine how well asthma is controlled and investigate what treatments are actually taken by patients diagnosed with asthma in 2 primary health care clinics in Barcelona. We also assessed whether adapting treatment to international guidelines1 and undertaking a basic educational intervention to inform the patients about asthma in a single dedicated visit could improve the degree of symptom control in such patients and reduce the use of health care services.
and/or chest tightness. Seasonal variation in symptoms and a family history of asthma or atopy helped guide diagnosis.11

Statistical Analysis

Initially, the sociodemographic and clinical characteristics of the patients included in the study were analyzed descriptively. The baseline characteristics of patients with complete follow-up and those who failed to attend the second visit were compared. Groups were compared with the Student t test in the case of quantitative variables and with the χ² test or Fisher exact test in the case of qualitative variables. The comparative analysis between the baseline visit and the follow-up visit was done with the McNemar test for paired data. The level of significance was set to .05 for all statistical tests. The statistical analysis was carried out using the SPSS program version 12.0.

Results

Baseline Visit

Of the 230 patients who answered the telephone call, 192 (83%) attended the clinic. Of those who attended, diagnosis of asthma was confirmed in 180, who comprised the patient population studied in the first visit. Table 2 presents the baseline characteristics of the patients: 70% were women, 42% were over 60 years old, 17% were regular smokers, 46% had only primary education, 8% were illiterate, and 75% were or had been manual workers. Skin prick tests had been done in 131 patients (73%), and 82 (63%) reported that the results had been positive for at least 1 antigen. A high percentage reported other allergic symptoms, the most common of which was rhinitis (46%) followed by conjunctivitis (42%). A significant or severe clinical reaction to acetylsalicylic acid had been experienced by 11% of the patients. As expected, 90% of the patients were attended by a physician of the Catalan health system—51% directly by the family physician and 44% by a pulmonologist. Eight percent were attended by a private physician through a health insurance company or other system. Only 22 patients reported following alternative medical treatment. Only 22% of the patients reported having received explanations about asthma, 37% said they had no written treatment plan, and only 14% had a plan to follow in the event of exacerbation of the disease. After excluding patients with systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg, the mean (SD) systolic blood pressure in the remaining 114 patients was 119 (73) mm Hg and the mean diastolic blood pressure was 73 (6) mm Hg.

The clinical characteristics at the baseline visit are described in Table 2. The second appointment was kept by 110 patients (61%). There were no significant differences between these patients and the 70 (39%) who did not keep the second appointment, except for drug allergy, which was more common in the group who kept the appointment (n=27, 25%) than in the other group (n=8, 11%) (P<.03), and reactions to acetylsalicylic acid, reported by 18 (16%) of those who kept the second appointment and 2 (3%) of those who only had significant changes available

### Table 2.

**Baseline Sociodemographic, Clinical, and Health Care Characteristics of the 180 Asthmatic Patients Attended in 2 Primary Health Care Clinics**

<table>
<thead>
<tr>
<th>Age, y</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>39 (19)</td>
</tr>
<tr>
<td>20-69</td>
<td>55 (30)</td>
</tr>
<tr>
<td>70-79</td>
<td>75 (42)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sex</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>126 (70%)</td>
</tr>
<tr>
<td>Men</td>
<td>54 (30%)</td>
</tr>
</tbody>
</table>

**Smoking habit**

- Non-smokers: 128 (71%)
- Smokers: 52 (29%)

**Type of Work**

- Professional/university graduates: 25 (14%)
- Manual: 20 (11%)
- Office worker/student: 45 (25%)
- Others: 15 (9%)

**Skill level**

- Skilled manual: 35 (19%)
- Skilled: 44 (24%)
- Manual: 101 (56%)

**Educational level**

- No education: 11 (6%)
- Primary: 31 (17%)
- Secondary: 35 (19%)
- Higher: 55 (30%)
- Professional/university: 20 (11%)

**Primary disease**

- Asthma: 180 (100%)

**Diabetes mellitus**

- Diabetes: 2 (1%)

**Other manifestations of hypersensitivity**

- Allergic rhinitis: 63 (35%)
- Conjunctivitis: 31 (17%)
- Eczema: 14 (8%)
- Urticaria: 12 (7%)
- Contact dermatitis: 10 (6%)

**Previous allergy studies**

- Skin prick tests available: 131 (73%)
- Positive skin prick tests: 82 (45%)

**Written treatment plan when plan**

- Written when plan available: 26 (14%)
- Written when plan needed: 154 (85%)

**Explanation of asthma**

- Written when plan needed: 22 (12%)
- Written when plan not needed: 158 (88%)

**List of substances to avoid**

- Written when list needed: 89 (50%)
- Written when list not needed: 191 (100%)

**Treatment guidelines received**

- Written when guidelines received: 39 (22%)
- Written when guidelines not needed: 141 (78%)

**Severity**

- I (mild intermittent): 46 (26%)
- II (mild persistent): 37 (21%)
- III (moderate): 13 (7%)
- IV (severe): 6 (3%)

**Positive skin prick tests**

- Positive: 82 (45%)
- Negative: 98 (53%)

**Other medications currently used**

- Antihistamines: 70 (39%)
- Nonsteroidal anti-inflammatory agents: 82 (45%)
- S-K (mizol, sulpiride, triamcinolone, iodine, and "cough syrup": 19 (10%)

**Treating physician**

- Family physician: 83 (51%)
- Pulmonologist: 70 (44%)
- Other physicians: 9 (5%)

**SPT results**

- Negative: 12/35 (35%)
- Positive: 36/82 (43%)

**Explanation of asthma**

- Written: 89 (50%)
- Written but not needed: 191 (100%)

**Other medications currently used**

- Antihistamines: 70 (39%)
- Nonsteroidal anti-inflammatory agents: 82 (45%)
- S-K (mizol, sulpiride, triamcinolone, iodine, and "cough syrup": 19 (10%)

**Type of Work**

- Homemaker: 64 (36%)
- Office worker/student: 58 (32%)
- Cleaner: 19 (10%)
- Food worker: 6 (3%)
- Textile worker: 5 (3%)
- Builder: 5 (3%)
- Baker: 4 (2%)
- Other: 19 (10%)
did not (P<0.006). Those who kept the second appointment were less frequently attended by a private physician (n=4, 4%) than those who did not (n=10, 14%) (P<0.02). The only difference in the treatment they were taking at the first visit was in intake of anticholinergic drugs, taken more frequently by those who attended the second visit (n=17, 15%) than by those who did not attend (n=4, 3%) (P<0.03). The reasons for not keeping the second appointment, despite arranging it during the first visit and calling by telephone a few days before the appointed day were as follows: 5 patients had not complied with treatment due to worries about the side effects of inhaled corticosteroids, 23 patients suffered laryngeal side effects from corticosteroid use, 22 patients had not complied with the prescribed treatment, 25 patients confirmed but did not attend, and 15 did not attend for unknown reasons.

Table 3 shows the treatment that the 180 patients were prescribed by the pulmonologist at the first visit according to GINA criteria. Table 4 shows the data on the degree of symptom control in the 4 months prior to the baseline visit and in the 4 months between this visit and the follow-up visit (second visit). It was found that, in this period, fewer visits had been scheduled (P<0.001) and fewer emergency visits to the physician due to exacerbation were reported (P<0.001). Likewise, fewer emergency visits to the primary health care clinic were required (P<0.001). Moreover, disease control at the follow-up visit was significantly better as reflected by the significantly lower severity (P<0.02). Between the 4-month periods before each of the visits, there were no differences with regard to having 7 consecutive days with symptoms or use of rescue medication for more than 7 days. As shown in Table 5, 4 months after the intervention, patients continued to follow a treatment that was significantly different from their previous one and this new treatment was better adapted to GINA guidelines.

### Discussion

One part of this study describes the clinical characteristics and treatments of a group of asthmatic patients diagnosed and attended in two primary health care clinics. The study also showed that adapting treatment to the recommendations of international guidelines, together with a brief explanation of the disease, led to fewer exacerbations and less use of health care services by the patients. These patients...
required fewer visits, whether scheduled or urgent, to their family physician and fewer emergency visits to the primary health care clinic.

Studies on educating asthmatic patients have shown that brief interventions of an educational nature (information only) do not have a significant impact on outcome unless this effort is accompanied by a plan for action: monitoring of the disease by the patients themselves, or regular check-ups. In contrast, interventions that require self-monitoring, whether of symptoms or peak flow, together with a plan of action for exacerbations, have been shown to be effective, and therefore the guidelines recommend that such measures be offered to asthmatic patients. In any case, it should be remembered that efficacy and effectiveness are not the same. Efficacy refers to the impact of a medication in optimum conditions, whereas effectiveness applies to the effects in everyday practice. In the Catalan health system, as in other health systems, application of these interventions is hindered by the short time—5 minutes—the family physician has for explaining what asthma is, prescribing the medication, explaining treatment, instructing the patients on how to administer the medication correctly, and finally, showing them how to monitor the disease themselves, either by paying attention to symptoms or measuring peak flow. In a real-life situation, it is therefore difficult to offer appropriate care to the asthmatic patient. Consequently, control of the disease in asthmatic patients is unsatisfactory as reflected in the present study.

In an attempt to improve this situation, we proposed that a pulmonologist schedule an appointment in the primary health care clinic with all patients diagnosed with asthma in order to adapt treatment to international guidelines, briefly inform the patient about the disease, and issue a basic written treatment plan for exacerbations. All these actions were completed in 5 minutes. The outcome of this intervention after 4 months was less use of health care services and a decrease in the severity of asthma in the patient population. This finding suggests that the patients, in addition to receiving better treatment, were better able to treat exacerbations by self-administration of more courses of oral corticosteroids compared to the period prior to the intervention ($P<0.001$). As a result, the patients required fewer scheduled and emergency visits to their family physician ($P<0.001$) and fewer emergency visits to the primary health care clinic ($P<0.001$). Given that patients with an exacerbation usually receive corticosteroids when they attend one of the emergency services, the recommendation to use a short course of such drugs if the exacerbation is not improved by adding short-acting $\beta$-agonists is effective at decreasing the burden on health services and can avoid the need for equal or even higher corticosteroid doses.

The one-off intervention of an expert can help improve control of bronchial asthma and encourage the follow-up of patients and caregivers. The expert is responsible for adapting treatment to the guidelines and briefly informing the patient about the disease. Such an intervention is indeed recommended by the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) and the Spanish Society of Family and Community Medicine (semFYC), and may be beneficial for the health care system. In addition to improving the control of symptoms, these measures may reduce the overall cost of this disease to the health care services. We should remember though, that 39% of the patients did not keep the second appointment, and we can only assess the effectiveness of the intervention in those who actually attended the follow-up consultation. We were able to ascertain that many of the patients did not come to the second visit because they had not complied with the prescribed treatment, a finding which suggests that the intervention was not very effective in these patients.

In the discussion of the clinical characteristics of the study patients, it should be remembered that the population corresponded to asthmatic patients who attended our primary health care clinics. This population accounts for only half the entire asthmatic population, that is, those diagnosed with the disease. Thus an additional 3% of the overall population must correspond to subjects with asthma that has yet to be diagnosed to make up the well-known figure of 6% for the prevalence of asthma. Indeed, 70% of the present sample were women, whereas women make up 52.9% of the asthmatic population in Spain. Similarly, a high percentage of these patients cared for in an outpatient setting for asthma are over 60 years old (42%), and such patients may seek medical attention more frequently because they have retired or because a greater percentage of them have been diagnosed with asthma after visits to the family physician for other reasons. In our population, 17% were smokers, a figure that while high is lower than the 31% of smokers who comprised the population of asthmatic patients who attended hospital emergency rooms (data submitted for publication). It should be pointed out, however, that the mean (SD) age of the population attending the hospital emergency rooms was 46 (28) years, lower than that of the present study population (59 (20) years).

Of note is the 8% of the population who were illiterate and that many of the patients (46%) had only completed primary education. Such patients will have greater difficulty reading, understanding, and following the instructions of their physician. Also of note is the high prevalence of jobs that require contact with cleaning products: homemakers comprised 35% of the overall population and cleaners represented 10%. Attention has been drawn to recent findings that have identified such products as a trigger of asthma attacks. Of the 131 patients who had undergone skin tests to detect possible atopy, 63% reported that at least 1 of the tests had been positive; that is, these patients had extrinsic asthma. Apart from finding that many of the asthmatic patients (70%) had undergone these tests, the figure of 63% for extrinsic asthma is high for this population if we bear in mind that 40% of a broad sample of the Spanish population between 22 years and 44 years who had undergone a methacholine test were
positive. It is also interesting that the patients showed a number of other manifestations of allergy; 46% reported rhinitis, 42% conjunctivitis, 27% urticaria, 23% eczema, and almost 20% some type of drug hypersensitivity. The increase in the percentage of patients population according to whether at least one skin test was positive, the percentages of other manifestations of atopy are 50% of rhinitis, 43% for conjunctivitis, 32% for eczema, 26% for urticaria. These percentages are somewhat higher than those with negative test results, that is, those with intrinsic asthma. It is also noteworthy that 11% of the patients reported that they were certain they had experienced an adverse reaction to acetylsalicyclic acid and 4% reported a probable reaction to this drug. In fact, it is known that up to 28% of asthmatic patients are hypersensitive to nonsteroidal antiinflammatory drugs if they undergo a challenge test with these drugs.

In the analysis of the treatments actually used by the patients (Table 3), we found that these patients were not receiving the recommended treatment even though guidelines are available. The question in the protocol was phrased to ask about the “medication that you are actually taking,” and so we were unable to determine whether this lack of compliance with the guidelines was because the medication was not prescribed or because the therapeutic compliance of the patients themselves was inadequate. The intervention of the pulmonologist served to adapt the medication to that recommended by the guidelines. We should point out that this adaptation will of course increase the use of inhaled corticosteroids and long-acting β-agonists, often through the use of combinations already on the market. This poses the question of what will happen in the coming years when long-acting β-agonists are used as long-term treatment because, according to some reports, such use was associated with an increase in severe exacerbations.

However, this association was not corroborated by a recent study. Furthermore, according to a recent study by Bouzy et al. in patients with persistent mild asthma (found in 49% of the patients in our study), differences in disease control over the course of a year were not found between those who concomitantly received inhaled corticosteroids, as recommended in the guidelines, and those who only used such drugs in the event of deterioration of symptoms. Continual use of such drugs has therefore been brought into question. It is also noteworthy in our study that many patients (25%) were actually taking, and so we were unable to determine whether this lack of compliance with the guidelines was because the medication was not prescribed or because the therapeutic compliance of the patients themselves was inadequate. The intervention of the pulmonologist served to adapt the medication to that recommended by the guidelines. We should point out that this adaptation will of course increase the use of inhaled corticosteroids and long-acting β-agonists, often through the use of combinations already on the market. This poses the question of what will happen in the coming years when long-acting β-agonists are used as long-term treatment because, according to some reports, such use was associated with an increase in severe exacerbations.

Given that this study presents level III evidence (uncontrolled study of a group of patients and after an intervention), further randomized, controlled studies should be done in patients, perhaps with 2 short successive interventions, to confirm these findings and, in particular, to corroborate the improvement in the degree of severity of disease in these patients.

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REFERENCES