Patients' understanding of the reasons for starting and discontinuing inhaled corticosteroids

Tanja T. Menckeberg,¹ Marcel L. Bouvy,^{1,2} Madelon Bracke,¹
Jacqueline G. Hugtenburg,³ Jan-Willem Lammers⁴ &
Jan A. M. Raaijmakers¹

¹Division of Pharmacoepidemiology and Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University, Utrecht, ²SIR Institute for Pharmacy Practice and Policy, Leiden, ³Department of Clinical Pharmacology and Pharmacy, Section Pharmacotherapy, VU Medical Centre, Amsterdam and ⁴Department of Pulmonary Diseases, Utrecht Medical Centre, Utrecht, the Netherlands

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Early discontinuation of treatment in new users of inhaled corticosteroids (ICS) has been widely discussed, but patients' reasons for this have not been investigated in depth.

WHAT THIS STUDY ADDS

- In contrast to what might have been expected, the majority of patients mentioned a wide range of symptoms or conditions as the reason for the start of ICS therapy.
- There is no clear indication for prescribing ICS in these patients.
- Most of these conditions are self limiting and may be expected to be of short duration, consequently a decrease in symptoms was the main and justifiable reason for discontinuing ICS.
- However, a non-negligible proportion of patients has significant residual symptoms and seems to be in need of continuous ICS use.

Correspondence

Dr Marcel L. Bouvy, PhD, Division of Pharmacoepidemiology and Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University, Utrecht, the Netherlands or SIR Institute for Pharmacy Practice and Policy, Leiden, the Netherlands.
Tel: + 31 30 253 7324
Fax: + 31 30 253 9166
E-mail: m.l.bouvy@uu.nl

Keywords

adherence, continuity of care, discontinuing treatment, inhaled corticosteroids, pharmacist, symptom experience

Received

22 June 2007

Accepted

11 February 2008

AIM

Although early discontinuation of treatment in new users of inhaled corticosteroids (ICS) has been widely discussed, the reasons for stopping have not been investigated in depth. We aimed to describe reasons for discontinuation from a patient's perspective in relation to their experience of symptoms at the time of the investigation.

METHODS

A cross-sectional study among new users that discontinued ICS use in the Netherlands was performed. Patients were interviewed by telephone, aiming to identify the symptoms for which they were prescribed ICS, the reasons for discontinuing treatment and the respiratory symptoms patients still experienced at the time of the survey. In addition, automated dispensing records of all patients were retrieved.

RESULTS

From 287 eligible patients, 230 (80.1%) were interviewed. Only 22 patients (9.6%) mentioned asthma as the reason for a first ICS prescription. A decrease in symptoms was the main reason for discontinuation (45%). Thirty patients (13%) reported clinically significant residual symptoms. These patients reported more seasonal variation of symptoms and were more often prescribed short-acting β_2 -agonists.

CONCLUSIONS

The majority of patients mentioned a wide range of symptoms and conditions, other than asthma or chronic obstructive pulmonary disease, as the reason for the start of ICS therapy. Most of these conditions may be expected to be of short duration. Not surprisingly a decrease in symptoms was the main, and justifiable, reason for discontinuing ICS. However, a non-negligible proportion of patients reported residual symptoms that suggest the need of continued ICS use. Physicians and pharmacists could cooperate in identifying those patients for which ICS are really indicated and motivate them to continue the use of ICS.

Introduction

Inhaled corticosteroids (ICS) are indicated for prophylactic treatment of patients with persistent asthma [1]. A trial of ICS is also indicated in patients with chronic obstructive pulmonary disease (COPD), who have a forced expiratory volume in 1 s of <50% and more than three exacerbations in the past 3 years [2]. International asthma and COPD treatment guidelines recommend long-term therapy with ICS [1, 2]. Poor compliance with ICS can lead to increased morbidity and mortality [3, 4].

Studies on continuous use of ICS comprise assessment of persistence [5, 6] and adherence [7, 8]. Van Staa *et al.* found that only 42.1% of patients in the UK and 31.1% in the Netherlands received a repeat prescription within the expected duration of the preceding ICS prescription [5]. Breekveldt *et al.* found that in a selected population of new users an even lower proportion of 17% continued ICS treatment after 1 year [6].

In general, nonpersistence and non-adherence have been shown to be associated with a lack of patients' and physicians' awareness, and patients' knowledge about the disease and treatment [9, 10]. Barber *et al.* found that the incidence of non-adherence was greater with new than with existing medication [9]. However, specific reasons for early discontinuation of ICS in new users have not been investigated in depth.

The aim of this study is to describe the reasons for early discontinuation of ICS from a patient's perspective and in relation to self-reported residual respiratory symptoms and use of rescue medication.

Materials and methods

Study design

A cross-sectional study was performed in 15 pharmacies in the Netherlands, located in both rural and urban regions.

Participants

New ICS users were defined as patients who did not fill an ICS prescription in the 2 years before a first ICS prescription. Both single ICS and combination preparations of ICS and long acting β_2 -agonists were considered an ICS prescription. Early discontinuation was defined as the absence of an ICS refill in at least the 6 months after this period. In the Netherlands patients are allowed to be dispensed a supply of inhalers sufficient for a maximum period of 3 months. Consequently, we determined discontinuing of ICS after a grace period of 3 months to be a total period of 6 months. The majority of patients in the Netherlands visit one regular community pharmacy, independently of prescriber, and pharmacy records are therefore virtually complete with regard to prescription drugs [11].

Procedure

Initially selected patients were contacted by telephone by their pharmacist. For patients that could not be contacted during pharmacy opening hours, at least one new attempt was made in evening hours. The telephone interview was conducted using a structured questionnaire. For patients aged < 14 years the parents completed the questionnaire.

Privacy

The local ethical review panel did not consider the questionnaire to such an extent invasive of the study participant's integrity that informed consent of the study subjects prior to the survey was necessary. The questionnaires were anonymized by use of a randomly assigned unique number for each patient. During the interview, patients were specifically asked for their consent to use the data anonymously for research purposes.

Questionnaire

We used the Asthma Control Questionnaire (ACQ) to assess patients' experience of symptoms [12]. The choice for this questionnaire was based on the original expectation that the majority of patients would be suffering from asthma. As we expected that some patients might not have asthma or might not be aware of the diagnosis of asthma, the interviewer would ask for 'respiratory symptoms' instead of 'asthma' when patients indicated another reason for prescribing of the ICS [12]. Patients responded on a seven-point Likert scale per item. The items are equally weighed and the test score is the mean of the scores of six items and therefore between 0 (no symptoms) and 6 (severe symptoms).

When applied in asthma, an ACQ score of ≥ 1.5 is regarded as not well-controlled disease [13]. In this study we used the same cut-off point to define patients with clinically significant symptoms that would justify continued ICS treatment.

Furthermore, the questionnaire comprised additional items on:

- 1 Symptoms or diagnosis at start ('For which symptoms or disease was this ICS inhaler prescribed?').
- 2 Reasons for discontinuation of ICS ('Is it correct that you have not refilled your ICS inhaler in the past 6 months? If correct and you have stopped using your inhaler; could you explain why you have?').
- 3 The seasonal variety of symptoms ('Please grade the level of symptoms for each season of the year; spring, summer, autumn, winter.' Responses are rated on a five-point scale, where 1 represents no symptoms and 5 represents very severe symptoms). Overall experience of symptoms was defined as the sum of the four separate scores and variation was expressed as the standard deviation. Patients who had any response in a particular

season that differed from the other seasons were classified as reporting seasonal variation.

The questions were phrased in a nonthreatening way. In a pretest, a questionnaire comprising open-ended questions was applied. The answers obtained were categorized and a definitive questionnaire was developed with multiple-choice items and an open-end option ('other'). Since questions were transparent and confined to reasons for start, stop and whether their symptoms subsided, it was not expected that patients would not be able to recall the events accurately.

Medication use

Automated dispensing records for up to 5 years preceding the survey of these patients were available. The number of prescriptions dispensed within the year of start of ICS for all respiratory medication and relevant comedication such as the number of prescriptions for oral corticosteroids, allergen extracts, antihistamines and systemic antibiotics were analysed. We calculated the total number of defined daily doses (DDDs) of ICS dispensed for each patient. DDDs of short acting β_2 -agonists (SABA) were calculated over the year before the first ICS prescription.

Statistical analysis

Descriptive statistics were calculated. χ^2 tests were applied for each categorical variable to test the difference between subgroups (responders and nonresponders).

Nonparametric methods, Wilcoxon and Kolmogorov-Smirnov, were performed for sample comparisons on skewed continuous variables (age, number of prescriptions). Differences were defined as statistically significant at $P < 0.05$.

Results

Baseline characteristics of responders

Within the 15 participating pharmacies, 287 (42.4%) out of 677 new ICS users did not refill any prescription within 6 months after the first prescription. Of these 287 patients, 230 (80.1%) were interviewed. The main reasons for non-response were that patients could not be contacted (9.9%), refused to participate (1.7%), had no time (1.4%) or had no interest (1.0%). Men and patients between 20 and 64 years old were slightly underrepresented among responders. However, differences between responders and nonresponders did not reach statistical significance. Responders and nonresponders did not differ with respect to their medication use as described in Materials and methods.

Almost one-fifth (18%) of the study population was <14 years old and therefore represented by a proxy (mother or father). About half the sample (49.1%) was >45 years old.

Table 1

Demographic variables, questionnaire items and medication use for responders

	Total sample (n = 230) (100%)
Demographic variables	
Gender (% female)	139 (60.4%)
Mean age ($\pm$ SD)	46.3 $\pm$ 25.5
Reasons for starting ICS therapy according to patient*	
Asthma	22 (9.6%)
Dyspnoea with or without wheezing	83 (36.1%)
Cough with or without sputum	59 (25.7%)
Cold, pneumonia or bronchitis	56 (24.3%)
Allergic rhinitis	3 (1.3%)
Other symptoms	12 (5.2%)
No answer provided	9 (3.9%)
Reasons for discontinuation according to the patient	
No symptoms experienced any more	107 (45%)
No answer provided	65 (27.3%)
ICS were not effective	8 (3.4%)
Side-effects	4 (1.7%)
Use when necessary	34 (14.3%)
Other	20 (8.4%)
Type of ICS used†	
Fluticasone	123 (52.6%)
Budesonide	20 (8.5%)
Beclomethasone	17 (7.3%)
Fluticasone + salmeterol	56 (23.9%)
Budesonide + formoterol	18 (7.7%)
ICS use (DDDs mean $\pm$ SD)	
Single preparation	24.1 $\pm$ 25.2
Combinations with long-acting β_2 -agonist	11.2 $\pm$ 19.4
β_2-agonists (DDDs mean $\pm$ SD)	
Short-acting β_2 -agonists (single and combination preparation)	15.5 $\pm$ 57.0
Long-acting β_2 -agonists	2.15 $\pm$ 12.4
Comedication (patients dispensed at least one prescription)	
Oral corticosteroids	14 (6.1%)
Oral antibiotics	135 (58.7%)
Antihistamines	48 (20.9%)

*Patients sometimes mentioned several (categories of) symptoms or diagnoses.

†Ten patients received two prescriptions, of whom four patients received two different preparations.

Reasons for starting ICS therapy according to patients

The majority of the sample did not mention a clear diagnosis as a reason for the ICS prescription. Only 22 patients (9.6%) mentioned asthma as the reason for a first ICS prescription. Almost comparable proportions of patients recalled dyspnoea with or without wheezing (36.1%), cough with or without expectoration (25.7%) or a cold, pneumonia or bronchitis (24.3%) as the reason for their prescription (Table 1).

Reasons for discontinuation

A substantial proportion of the sample (27.3%) could not give a clear explanation for discontinuing ICS. For 107 (45%) patients a (complete) decrease of symptoms was the

main reason for discontinuing ICS use. Thirty-four patients (14.3%) claimed to use ICS intermittently only when necessary, and eight patients (3.4%) experienced a lack of effect of the ICS (Table 1).

Symptom experience

Fourteen subjects (6.1%) were excluded from this analysis, as they did not complete the questionnaire. The majority of patients (136; 59.1%) reported being completely free of symptoms in the period prior to the survey. However, 30 patients (13.0%) had a test score ≥ 1.5 and most probably experienced clinically significant symptoms (Table 2) [13].

The latter group of patients reported more often symptoms or disease with a probably more chronic course

Table 2

Comparison of patients with and without probably clinical relevant symptoms according to test score (cut-off point = 1.5)

	Test score < 1.5 n = 186	Test score ≥ 1.5 n = 30
Gender (% female)	111 (59.7%)	21 (70.0%)
Mean age $\pm$ SD	42.2 $\pm$ 24.1	44.5 $\pm$ 21.9
Patients younger than 45 years	98 (52.7%)	12 (40.0%)
Patient questionnaire items		
Reasons for starting ICS therapy according to patient		
Asthma	16 (8.6%)*	4 (13.3%)
Dyspnoea with or without wheezing	62 (33.3%)	15 (50.0%)
Cough with or without sputum	55 (29.6%)*	4 (13.3%)
Reasons for discontinuation		
No symptoms experienced	95 (51.1%)*	5 (16.7%)
Seasonal variation of symptoms according to the patient		
Overall severity throughout the year (sum)	4.9	10.8
Mean standard deviation of season scores within a patient	0.23*	0.84
No seasonal variation, all seasons low level of symptoms	145 (78.0%)	2 (6.7%)
Seasonal variation†	30 (16.0%)	14 (46.7%)
No seasonal variation, all seasons high level of symptoms	2 (1.1%)	10 (33.3%)
Medication use		
ICS use (DDDs mean $\pm$ SD)		
Single preparation	24.5 $\pm$ 25.0	23.6 $\pm$ 28.9
Combinations with long-acting β_2 -agonist	10.7 $\pm$ 19.2	13.2 $\pm$ 16.4
Reliever medication (DDDs mean $\pm$ SD)		
Short-acting β_2 -agonists (single preparation)	9.03 $\pm$ 16.8	29.8 $\pm$ 60.2
Short-acting β_2 -agonists (combination preparation)	–	0.6 $\pm$ 3.1
Daily controller medication (DDDs mean $\pm$ SD)		
Long-acting β_2 -agonists	2.18 $\pm$ 12.1	3.0 $\pm$ 16.4
Co-medication (% patients dispensed at least one prescription)		
Oral corticosteroids	11 (5.9%)	3 (10.0%)
Oral antibiotics	105 (56.5%)	18 (60.0%)
Antihistamines	37 (19.9%)	10 (33.3%)

Fourteen patients were excluded with more than one missing item in the questionnaire. * $P < 0.05$. †Any response that differed from the other seasons was classified as reporting seasonal variation.

(dyspnoea and asthma) as the reason for filling an ICS prescription ($P = 0.043$) (Table 2). Moreover, these patients more often used their ICS intermittently (69.7% vs. 30.3%) and more often received prescriptions of SABA (50% vs. 34.4%) ($P < 0.05$).

Most patients did not have a seasonal pattern and indicated no, or only moderate symptoms in each season (68.1%). Forty-four patients (20.4%) reported seasonal variations and 12 patients (5.6%) experienced quite severe symptoms in each season. Patients with a test score ≥ 1.5 showed more seasonal variation ($P < 0.001$) and more frequently reported asthma as the reason for ICS use ($P = 0.04$) (Table 2). None of the patients who reported quite severe symptoms in each season reported asthma as the reason for a first ICS prescription. Almost all of these patients ($n = 9$) were aged ≥ 45 years.

Discussion

Although many studies have described poor adherence, reasons for early discontinuation of ICS among new users have not been studied in depth. To understand and possibly find clues to improved adherence to ICS treatment, we identified reasons for early ICS discontinuation from the perspective of the patient. It was expected that ICS would have been prescribed to the majority of patients for the treatment of obstructive lung diseases (i.e. asthma or COPD). However, the majority of patients that started ICS treatment did not mention a clear diagnosis with an approved indication for ICS use. Less than one-tenth of our sample mentioned that they were prescribed an ICS for asthma and none mentioned COPD. In contrast, patients most frequently mentioned symptoms such as dyspnoea and cough as reasons for the start of ICS therapy. Apparently, in the majority of cases, a clear diagnosis referring to a chronic condition that requires continuous treatment seemed to be absent. Consequently, from a patient's perspective a (complete) decrease in symptoms seemed a logical and appropriate reason for early discontinuation of ICS. This puts previous findings that new users of ICS often discontinue treatment within 1 year in perspective [6]. Since previous studies reporting high discontinuation rates have been based on the premise that ICS are usually prescribed for chronic use, a general idea of blame has evolved against patients who do not persist. However, from our study it can be concluded that ICS are often prescribed in case of symptoms or conditions as dyspnoea, cough, cold, bronchitis or pneumonia. Although these seem questionable reasons for prescribing ICS, in clinical practice patients presenting with these symptoms pose some diagnostic challenges. Moreover, the statement in the Global Initiative for Asthma guidelines that asthma should be considered if a patient's cold repeatedly 'goes to the chest', takes >10 days to clear up, or the patient improves when asthma medication is given, might support the use of ICS

based on a less certain diagnosis [1]. Thus some of the patients who reported these nonspecific respiratory symptoms might, if correctly diagnosed, suffer from asthma or COPD. It seems plausible that especially patients that experienced clinically relevant symptoms might belong to this category.

There might be several possible explanations for our findings. First, patients might not remember correctly for what condition their ICS was prescribed. However, few patients mentioned that they could not remember. Second, the physician might not have discussed a diagnosis and the choice of ICS treatment with the patient. This could be because the physician was not (yet) certain about the clinical diagnosis and ICS could have been given as a trial. In this scenario, the physician should have ordered the patient back to evaluate ICS treatment. Finally, it cannot be ruled out that some patients deny having asthma or a related diagnosis, although it was mentioned by their physician.

As described, most patients experienced no symptoms at all at the time of the interview. One-fifth of the population mentioned seasonal variation in the occurrence of symptoms. However, a substantial proportion of patients reported residual clinically significant symptoms and could be in need of continued ICS use. This view is supported by the fact that this subgroup of patients more frequently used ICS intermittently and more frequently filled a prescription for SABA [1]. This is in line with previous findings that patients adjust their treatment regimen with the variety and severity of their respiratory symptoms [14]. However, temporarily discontinuing treatment is, according to treatment guidelines, allowed only for patients with intermittent asthma (symptoms occurring less than once a week). Patients with persistent symptoms should lower the ICS dose only during periods with fewer symptoms [1]. Even patients with probable longer duration of asthma than in our study have been found to regard their disease as episodic and consequently did not manage their asthma as a chronic disease [15].

Implications

This study has shown that in daily clinical practice the use of ICS is not restricted to chronic indications such as asthma and COPD. Therefore, adherence to ICS treatment should preferably be studied with the disposal of an accurate diagnosis. Conclusions derived from studies that did not incorporate diagnosis probably overestimate non-compliance with ICS in chronic disorders.

However, the relatively large number of patients that have discontinued ICS, because symptoms are under control, should not misguide healthcare providers in missing those patients that remain uncontrolled: the latter patients need continuous monitoring, a key component of asthma management [1, 16]. Lack of continuity of care has been shown to affect patient care adversely [17]. Furthermore, this study suggests that intermittent use of ICS and

concomitant use of β_2 -agonists could indicate patients that are not well-controlled. These patients could benefit from increasing their intake of ICS.

Patients should be informed about why a particular treatment is initiated. To ensure adherence, full comprehension of the underlying disease, the purpose of treatment and a full discussion on the benefits and possible side-effects are essential. When considering patients presenting with nonspecific symptoms such as in our study sample, further evaluation of the presentation of symptoms is important in order to distinguish patients with asthma from those with other underlying diseases. A positive family history of asthma; variability of symptoms; precipitation by nonspecific irritants such as smoke, fumes, strong smells, or exercise; worsening at night; and responding to appropriate asthma therapy strongly suggest an asthma diagnosis [1]. This requires a thorough discussion on patients' experiences of symptoms, and their evolution in time should preferably be monitored. Moreover, the stepwise approach to asthma management recommended in the guidelines [1] necessitates regular review of treatment once asthma is under control [18]. When monitoring patient's self-management and control, the participation of pharmacists has been shown to improve the treatment regimen and the experience of symptoms [19–22]. The routine telephone review of disease control by either a physician or pharmacist increases the number of patients being monitored, the early detection of poor control and patient satisfaction [23–25]. To optimize individual disease management, pharmacists' knowledge of the individual patient's treatment goals is essential for the correct interpretation of a patient's medication use and disease control. If pharmacists are informed on the treatment goals the physician and patient have agreed upon, they can detect and alarm the physician when a patient's actual medication use deviates from what is expected [20]. Although further research is needed to embed the pharmacist in continuous provision of care for patients with chronic pulmonary disease, this study has demonstrated how pharmacists can contribute to detecting patients who need improvement of disease control.

Competing interests

T.T.M. has received an unrestricted grant for research from GlaxoSmithKline. M.L.B. has received unrestricted grants for research from GlaxoSmithKline and AstraZeneca. M.B. has received an unrestricted grant for research from GlaxoSmithKline. J-W.L. has received unrestricted grants for research from GlaxoSmithKline and AstraZeneca. J.A.M.R. is part time professor at the University of Utrecht and director external scientific collaborations for GlaxoSmithKline in Northern Europe, and holds stock in GSK.

The authors wish to acknowledge the pharmacies that have participated, S.L. Baal, MSc, C. van Kan and C. Zonnenberg for their contribution to data collection. SIR Institute for Pharmacy

Practice and Policy, Leiden, the Netherlands received an unrestricted grant from GlaxoSmithKline, Zeist, the Netherlands.

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