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Original Article

Changed terms for drug payment influenced GPs' diagnoses and prescribing practice for inhaled corticosteroids

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KEY MESSAGE:

- Patients with mild COPD often use inhaled corticosteroids without a need for them.
- A clinical audit including spirometry was useful for identifying overuse of inhaled corticosteroids.
- Altered diagnostic criteria for drug cost reimbursement influence GPs' diagnostic labelling.

ABSTRACT

Background: Inhaled glucocorticosteroids (ICS) are first-line anti-inflammatory treatment in asthma, but not in chronic obstructive pulmonary disease (COPD). To restrict ICS use in COPD to cases of severe disease, new terms for reimbursement of drug costs were introduced in Norway in 2006, requiring a diagnosis of COPD to be verified by spirometry.

Objectives: To describe how GPs' diagnoses and treatment of patients who used ICS before 2006 changed after a reassessment of the patients that included spirometry.

Methods: From the shared electronic patient record system in one group practice, patients ≥ 50 years prescribed ICS (including in combination with long-acting beta2-agonists) during the previous year were identified and invited to a tailored consultation including spirometry to assure the quality of diagnosis and treatment. GPs' diagnoses and ICS prescribing patterns after this reassessment were recorded, retrospectively.

Results: Of 164 patients identified, 112 were included. Post-bronchodilator spirometry showed airflow limitation indicating COPD in 55 patients. Of the 57 remaining patients, five had a positive reversibility test. The number of patients diagnosed with asthma increased (from 25 to 62) after the reassessment. A diagnosis of COPD was also more frequently used, whereas fewer patients had other pulmonary diagnoses. ICS was discontinued in 31 patients; 20 with mild to moderate COPD and 11 with normal spirometry.

Conclusion: Altered reimbursement terms for ICS changed GPs' diagnostic practice in a way that made the diagnoses better fit with the treatment given, but over-diagnosis of asthma could not be excluded. Spirometry was useful for identifying ICS overuse.

Keywords: Diagnosis, COPD, asthma, treatment, general practice

INTRODUCTION

Asthma and chronic obstructive pulmonary disease (COPD) are two separate diseases in terms of aetiology and pathophysiology, with different diagnostic and management strategies (1,2). In clinical practice, however, they may sometimes be hard to differentiate (3). Stable asthmatics usually have normal spirometry findings and hyper-responsiveness testing with histamine or methacholine is rarely performed in general practice (4,5). The frequency and clinical impact of the overlap between asthma and COPD have been emphasized (6). In chronic asthma, long-term inflammation over time may lead to a remodelling of the lower respiratory tract quite similar to that seen in COPD. This can impair respiratory function as measured by spirometry, i.e. less reversibility after inhalation of a beta2-agonist (7–9). Therefore, there may be considerable overlap between the two diagnoses, particularly in elderly patients (1,10,11).

Inhaled corticosteroids (ICS) are generally not recommended for COPD except for patients with severe COPD and frequent exacerbations, and there are good

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reasons to withhold the treatment in mild or moderate stages of COPD (1,12). However, ICS have been marketed heavily, and in situations with diagnostic uncertainty, it may be tempting for a general practitioner (GP) to add ICS to the medication list for patients with pulmonary obstruction. However, overtreatment with ICS is problematic because of both unnecessary costs and possible side-effects including dysphonia, thrush, cough, osteoporosis, adrenal suppression and adverse ocular effects (13,14). ICS therapy also increases the risk of pneumonia in patients with stable COPD (15).

In Norway in 2006, separate reimbursement codes for asthma and COPD were introduced and it became mandatory for drug cost reimbursement that the diagnoses should be confirmed by spirometry. The principle became that costs for ICS, alone or in combination with long-acting beta2-agonist (LABA), should only be reimbursed with a diagnosis of asthma. Patients with severe COPD (with forced expiratory volume in one second (FEV_1) less than 50% predicted by spirometry) could also be reimbursed, but only after a special and individual application. Physicians were, therefore, urged to reconsider their prescribing practice for patients with obstructive lung diseases to bring their prescription practice into accordance with the new regulations.

As clinicians, it was a challenge to comply with the new reimbursement regulations because of difficulties in identifying COPD patients who also suffered from asthma or who might benefit from using ICS for other reasons (16). Identification of COPD patients and discontinuation of ICS might not be a clinically straightforward decision. Therefore, a quality assurance project was undertaken, a clinical audit, in a GP group practice, focusing on middle-aged and elderly patients who were using ICS (ICS/LABA included), intending to comply with the new regulations. The aim of this study was to investigate how the implementation of the new reimbursement terms affected GPs' use of diagnoses for patients using ICS.

METHODS

Selection of study subjects

The study was undertaken in one group practice just outside Oslo, Norway, where approximately 8 100 patients were listed with six GPs. From the shared electronic patient record (EPR) database, all patients of 50 years and over were identified who had been prescribed ICS (including ICS in combination with long-acting beta2-agonist) during a one-year period before the regulation was put into practice (1 October 2006). In October 2006, all identified ICS users were sent a letter informing them about the new reimbursement regulations and an invitation to a tailored consultation with their GP to assess their respiratory illness.

Measurements and analysis

Tailored consultations, undertaken in October to December 2006, included the patients' history, physical examination and spirometry with reversibility testing. The patients' previous pulmonary diagnoses were recorded. Patients were instructed not to use any inhaled medications on the day of investigation prior to spirometry. The spirometry was carried out by trained staff in accordance with the criteria of the American Thoracic Society and the European Respiratory Society (17). The spirometer used was a Microloop II with Spirare® software and the European Coal and Steel Community reference for spirometry was used (18). Reversibility tests were performed 20 min after patients inhaled 0.4 mg salbutamol. Reversibility was defined as increased forced expiratory volume in one second (FEV_1) of $\geq$ 12% and 200 ml (2). The spirometry criterion for COPD was based on the GOLD guidelines and was a ratio of FEV_1 to forced vital capacity (FVC) less than 0.7 after bronchodilation (1). Based on predicted FEV_1%, patients were categorized to COPD stage based on the GOLD guidelines (1). Norwegian reference values for spirometry were applied (19). Data from the tailored consultation were recorded from each patient's medical record. The decision about follow-up of findings was left to individual GPs in collaboration with their patients. In April 2008, one year and three months after the audit was completed; a retrospective EPR data search was performed regarding GPs' diagnoses and prescribing patterns for patients who had participated in the clinical audit. Simple bivariate statistics such as chi-square tests were used for comparing proportions. Statistical significance was set at 0.05.

Ethics

All patients signed an informed consent giving the opportunity to analyse and publish the results at an aggregated level that did not compromise patients' anonymity. The study was presented to the Regional Committee for Medical and Health Research Ethics, South-East Norway, who judged this to be a clinical audit project, and therefore, without the need for formal approval by the committee.

RESULTS

The search of the shared EPR database revealed that 164 patients of 50 years and older (mean age: 66 years, range: 50–88 years) had been prescribed ICS the year before the 2006 regulation. Of the 164, 114 (69.5%) patients attended the tailored consultation. Of the 50 non-attendees, 14 no longer used ICS; three were too ill to participate; two were deceased; two had changed to a GP in another practice; one was followed up by the pulmonary clinic at the hospital, and one letter was

returned because of an unknown address. Of the remaining 27 non-responders (mean age: 73, range: 50–94 years; females 44%), 13 had received only a single ICS prescription. Two patients were excluded from analysis because of incomplete spirometry data. The mean age of the 112 patients included in the analysis was 65 years (range: 50–88 years); 57% were women; 46% were daily smokers, 35% previous smokers and 19% never smokers.

Post-bronchodilator spirometry revealed COPD (FEV_1/FVC <0.7) in 55 patients (Table 1). Reversibility $\geq 12\%$ and 200 ml was found in 13 patients, of whom eight also met the spirometry criteria for COPD (Table 1). Fifteen of the COPD patients met the criteria for GOLD stage 3–4 (severe or very severe COPD); 30 were in stage 2 (moderate COPD), and 10 were in stage 1 (mild COPD).

The clinical outcome of this exercise as recorded in retrospect was discontinuation of ICS in 31 (27.7%) of the 112 patients (Table 1), of whom 20 (64.5%) had mild to moderate COPD, seven (22.6%) had no history, symptoms or signs indicating obstructive lung disease and the remaining four (12.9%) had episodic asthma without the need for long-term ICS treatment. One year and three months after this audit, we reviewed the electronic patient records (EPRs) of these 31 patients and ICS had been restarted in only one because of relapse of asthma.

The distribution of the GPs' diagnoses recorded in EPRs changed significantly after the implementation of the new reimbursement terms (Table 2). The proportion of patients who were diagnosed with asthma more than doubled. Among the 112 patients, 25 were labelled as asthmatic before the 2006 regulation compared with 62 afterwards, of whom 25 in fact, had spirometry findings suggesting COPD. The proportion with a COPD diagnosis increased only slightly (Table 2) while formerly used diagnoses such as chronic bronchitis, chronic cough, or pulmonary fibrosis had become considerably less common.

Table 1. Spirometry findings in 112 patients treated with inhaled corticosteroids (ICS) in primary care, and the continuation and discontinuation of ICS after the spirometry results were known to the GP.

FEV1/FVC	Reversibility test	n	ICS continued (%)	ICS discontinued (%)
<0.7	Negative	47	27 (57)	20 (43)
	Positive	8	8 (100)	0 (0)
≥ 0.7	Negative	52	41 (79)	11 (21)
	Positive	5	5 (100)	0 (0)

Table 2. Diagnosis given to 112 patients who had been using inhaled corticosteroids (ICS)[a] for pulmonary problems before and after the 2006 regulation stating that ICS costs would be reimbursed for asthma but in general not for COPD.

Diagnoses	Before 2006 regulations (%)	After 2006 regulations (%)
Asthma	25 (22.3)	62 (55.4)
COPD	18 (16.1)	29 (25.9)
Other[b]	69 (61.6)	21 (18.8)

[a]ICS alone and ICS combined with beta2-agonist.
[b]Diagnoses other than asthma and COPD, i.e. chronic bronchitis, chronic cough, breathing problems, pulmonary fibrosis.

DISCUSSION

Main findings

While underdiagnosis and undertreatment of asthma or COPD in primary care have been highlighted in the literature (20,21), over-diagnosis and overtreatment are rarely addressed (11). The results suggest that the incidence of overtreatment with ICS may have been significant as it was possible to discontinue ICS treatment in more than a quarter of the treated patients.

Re-introduction of ICS was only necessary in one patient during the following year. This supports the notion that withdrawal of ICS can be safe as underlined in a recent meta-analysis (22).

Findings revealed that physicians tend to give a diagnosis that fits with the treatment given, rather than vice versa. When an asthma diagnosis became a prerequisite for prescribing ICS, the number of ICS-using patients with this diagnosis increased considerably.

Diagnostic challenges

With spirometry, the diagnoses of asthma and/or COPD in only about half of the ICS users were confirmed. The remaining patients showed neither airway obstruction nor a positive reversibility test. This group may in part represent patients previously categorized as COPD in GOLD stage 0 (i.e. chronic airway symptoms with normal spirometry) (23). This stage has been omitted from the COPD classification because of lack of evidence that it predicted further COPD development, a decision that may be questioned (1,20). A large fraction of those patients with normal spirometry were probably asthmatics in stable periods without current airway obstruction. According to the Global Initiative for Asthma (GINA), a positive reversibility test is an important criterion for asthma, but detecting this often requires several tests over time (2). In Norwegian general practice, the diagnosis of asthma is commonly established based on patients' symptoms and history without confirmation by spirometry (24). This is also current practice at the studied health centre. The quality of asthma diagnoses may, therefore, be questioned.

About one in seven of the COPD patients had a positive reversibility test, which may partly represent long-lasting asthma with irreversible structural changes and permanent airway obstruction (6,25–27). Persistent asthma may also have been present in some patients with post-bronchodilator FEV_1/FVC <0.7 and a negative

reversibility test. Bronchodilator reversibility is also found in moderate to severe COPD, and the distinction of chronic asthma with limited reversibility, therefore, remains notoriously difficult (28).

Labelling effects of reimbursement regulations

A dramatic shift in the GPs' use of diagnostic labels after the 2006 regulation was observed. Patients with COPD as defined by spirometry were prescribed ICS because of 'asthma.' This probably reflects that physicians tend to give a diagnosis that fits with a treatment rather than vice versa. There may be several reasons for this practice. First, the 2006 regulation was controversial, and some GPs did not agree with the health authorities in this case. Second, this regulation was not at all welcomed by the ICS manufacturers, and the industry plays an important role in shaping physicians' opinions about medication-related issues (29). Third, GPs usually perceive themselves as the patients' advocate. Use of costly ICS that is easily available without personal cost only for patients with confirmed asthma may, therefore, have significant economic implications for patients who did not meet the new reimbursement terms. Fourth, GPs' diagnostic behaviour may be explained by concerns related to preserving the GP–patient relationship, leading to unwillingness to admit previous inappropriate prescribing and an eagerness to please their patients. A fifth and maybe the most important explanation may be that GPs often find it hard to distinguish asthma from COPD, particularly in older patients. Prescribing ICS may, therefore, represent a therapeutic strategy to play safe in a clinical situation characterized by diagnostic uncertainty. Misdiagnoses are known to occur for primary care patients with respiratory problems (30).

After this audit, in January 2011, the Norwegian terms for ICS cost reimbursement were changed again. From this time, ICS/LABA may be prescribed without individual application for patients with moderate and severe COPD if they have had several exacerbations and a predicted FEV_1 less than 60% (before a reversibility test) on spirometry.

Strengths and limitations

This quality assurance project within one group practice has several limitations that must be taken into account when interpreting the results. It remains unclear to which extent findings are broadly representative for Norwegian general practice. However, as one of the GPs (SR) has a long-term interest in obstructive pulmonary diseases, it is believed the performance in this field is not inferior to the average Norwegian general practice.

Suboptimal spirometry performance is another possible limitation (31,32). However, all staff who conducted the spirometry investigations had been trained for the task (32). Therefore, it is regarded as unlikely that the spirometry done in the practice was below the average standard seen in primary care.

The spirometric GOLD criteria for defining and grading of COPD in elderly people have been questioned because age-related changes in the FEV_1/FVC ratio are not taken into account (33). This may lead to increasing numbers of false-positives with advancing age (32). This is probably relevant here because of the average age of 66 years in participating patients.

Only one patient who had ICS treatment discontinued had to restart this medication within the following year. Restart of ICS prescribed by doctors outside the group practice could in theory have taken place, but would probably be recorded in the EPR. Worsening of symptoms because of discontinuation of ICS was, therefore, a minor problem.

Conclusion

Results suggest that the incidence of overtreatment with ICS may be significant in middle-aged and elderly patients. Although a diagnosis of COPD and/or asthma could be confirmed in only half of the ICS-using patients, reassessing the GPs' clinical diagnoses by a tailored consultation including spirometry was an effective measure to allow revised treatment in more than a quarter of the patients on ICS therapy. This audit also highlights how GPs' diagnoses are challenged by formal regulations and that this may result in a tendency to adjust the diagnosis to the treatment given, instead of vice versa.

AUTHORS' CONTRIBUTIONS

LGD planned and directed this trial and is responsible for data analysis and preparation of the initial manuscript. SR had the original idea for this project and performed the study together with LGD. HM supervised LGD during analysis and interpretation of the spirometry results. JS supervised the project from planning to the preparation of the final manuscript. All authors have approved the final manuscript.

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