Feasibility of spirometry and reversibility testing for the identification of patients with chronic obstructive pulmonary disease on asthma registers in general practice

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There is renewed interest in the diagnosis of chronic obstructive pulmonary disease (COPD) within primary care. Primary care physicians have difficulty distinguishing asthma from COPD. We tested the feasibility of using spirometry and, if appropriate, reversibility testing, to identify patients with COPD on asthma registers in primary care.

We carried out a cross-sectional study in three inner-city group practices in east London. Three hundred and twenty-eight patients aged 50 years and over on practice asthma registers were invited to attend for spirometry and, if appropriate, a trial of oral corticosteroids. The main outcome measures were: feasibility of carrying out spirometry; lung function; severity of COPD; prior diagnosis of COPD; response to a corticosteroid trial; quality of life.

One hundred and sixty-eight of 328 (51%) patients attended for spirometry. According to British Thoracic Society criteria, 58 (34%) patients had normal spirometry at the time of assessment; 40 (24%) had active asthma and 57 (34%) had COPD. Thirteen patients (8%) were unable to perform spirometry. Of 57 patients with COPD 30 (53%) had mild, 15 (26%) had moderate and 12 (21%) had severe disease. Twenty-three of 57 (40%) patients with COPD on spirometry had this diagnosis recorded prior to the study. New diagnoses of COPD were more likely in those with mild or moderate disease (P<0.05). Twenty-three of 57 (40%) patients with COPD completed a corticosteroid trial: one showed significant reversibility of lung function.

Spirometry was feasible and helped identify patients with COPD on asthma registers in these inner-city practices. Patients aged 50 years and over on asthma registers had a wide spectrum of lung function with considerable diagnostic misclassification. Some patients with normal lung function when tested may have had well controlled asthma. New diagnoses of COPD were mainly in those with mild or moderate disease.

Introduction

Chronic obstructive pulmonary disease (COPD) places an enormous burden on healthcare (1). Deaths from COPD outnumber those from asthma by more than tenfold (2,3). Patients with COPD commonly present in primary care, but a reliance on presenting symptoms and lack of diagnostic facilities makes it difficult for primary care clinicians to distinguish between COPD and asthma (4), particularly for patients with features of both conditions. Practice asthma registers may therefore include some patients with COPD who may benefit from different management. Publication of guidelines has renewed interest in the identification of patients with COPD (5,6). Recent emphasis on asthma management may have left many older patients with unrecognized COPD receiving sub-optimal care. There is increasing interest in the use of spirometry in general practice (7,8).

The aim of our study was to test the feasibility of carrying out spirometry and, if appropriate, reversibility testing, to identify patients with COPD in patients aged 50 years and over on practice asthma registers.

Methods

Three inner-city east London group practices with an interest in asthma took part. The practices had list sizes of
5004, 10 512 and 6977 patients respectively, with similar distributions of patient ages. Practice asthma registers comprised 85, 147 and 292 patients aged 50 years or over respectively (8.6%, 8.2% and 20.1% of the practice populations in that age group).

To detect a 10% misclassification rate of patients on registers, with 85% certainty at 5% significance, we needed to test 170 patients. To achieve this target, we sent written invitations outlining the study to 328 patients aged 50 years or over on the practices’ registers. These comprised all 85 and 147 patients from the registers of the first two practices, and a one in three sample (96 patients, using a random number method) from the third. We excluded four patients over 75 years in the third practice since they were involved in another research trial.

We invited patients to attend up to three sessions with a respiratory nurse at their surgery. The nurse instructed patients to omit inhalers for 12 h before visits. The nurse detailed assessments in patient records. The local ethics committee approved the study was part of routine care.

We tested lung function using two identical hand held storage spirometers Vitalograph 7120 (Buckingham, U.K.), according to European Respiratory Society (ERS) guidelines (9) (best of three readings within 5%), calibrated using identical methodology (three discharges of a Vitalograph II calibration syringe before each session). Little or no recalibration of instruments was needed between sessions. Patients stood during tests and nose-clips were not used. The instrument incorporates normal values for patients over 70 years of age (10). Volume/time curves were printed for each patient immediately after each had completed spirometry. Where there was uncertainty, these traces were used to review technical success of spirometry and diagnostic categories.

THE FIRST PRACTICE VISIT: BRONCHODILATOR REVERSIBILITY TESTING

The nurse took a respiratory history and asked patients to complete the St. George’s Respiratory Questionnaire (SGRQ) (11). The SGRQ is a validated measure of health status for patients with asthma and COPD, consisting of 50 items with 76 weighted responses and three component scores—symptoms, activity and impact. A total score of 100 represents maximal disability.

After baseline spirometry, patients received 2.5 mg of nebulized salbutamol; followed 20 min later by spirometry to assess reversibility. Patients with good lung function [forced expiratory volume in 1 sec (FEV₁) < 75% predicted] and those with reversibility of impaired lung function (at least 15% and 200 ml), termed ‘active asthma’, took no further part. Those already taking oral steroids and those unable to perform spirometry were also excluded.

Patients with FEV₁ < 75% predicted and reversibility of less than 15% and 200 ml were defined as having COPD [based on British Thoracic Society (BTS) draft guidelines at time of study design; the BTS subsequently increased this criterion to FEV₁ < 80%]. These patients were invited to continue in the study. Whilst the BTS guidelines recommend the additional criterion of a FEV₁ forced vital capacity (FVC) ratio of less than 70%, piloting with review of spirometry traces by a respiratory specialist (JW) showed this limit to exclude patients with COPD who had cut short their FVC, giving a spuriously raised ratio. We therefore did not apply this criterion. We classified the severity of COPD according to FEV₁: mild (FEV₁ 60–75% predicted), moderate (40–59% predicted) or severe (<40% predicted).

We searched records of patients found to have COPD on spirometry for a diagnosis of COPD recorded as an active problem prior to the study.

The nurse asked patients with COPD on spirometry to stop inhaled corticosteroid treatment and return in 1 month, and gave written instructions in the event of an exacerbation. Patients experiencing an exacerbation (defined as development of new respiratory symptoms or worsening of stable symptoms) during this period restarted inhaled corticosteroids and were discontinued from the study.

THE SECOND AND THIRD PRACTICE VISITS: CORTICOSTEROID TRIAL

At the second visit, patients underwent spirometry, and were offered 50 mg of oral prednisolone daily for 14 days or 500 μg of inhaled beclomethasone dipropionate twice daily via large volume spacer for 6 weeks. Compliance was assessed by questioning patients directly. At the third visit, steroid response was assessed by spirometry, a positive response being an improvement in FEV₁ of at least 15% and 200 mls.

Lung function and quality of life data were entered onto Microsoft Access (Redmond, U.S.A.) and AppleMac (California, U.S.A.) databases respectively. SPSS (Woking, U.K.) was used for statistical analyses. The Sidak test was used to allow for multiple comparisons of quality of life scores between patients.

Results

ATTENDERS AND NON-ATTENDERS

One hundred and sixty-eight of 328 (51%) invited patients attended for assessment. Non-attenders were not significantly more likely to be male and current smokers than attenders (38% vs. 32% male and 40% vs. 30% current smokers respectively). Non-attenders were, on average, younger than attenders (means 63 vs. 67 years. P=0.001). The most common reasons for non-attendance were difficulty contacting patients [59 (18% of all invited)] or refusal to take part [58 (18%)]. For the majority of those whom we could not contact (39/59), we either had an
incorrect telephone number or patients did not have a telephone.

THE FIRST PRACTICE VISIT: BRONCHODILATOR REVERSIBILITY TESTING

Of the 168 patients assessed, by British Thoracic Society criteria, 58 (34%) had normal lung function, 40 (24%) had obstruction reversible by bronchodilator (active asthma) and 57 (34%) had obstruction irreversible by bronchodilator (COPD) (Table 1). Thirteen patients (8%) could not perform spirometry, either because of language difficulties or problems co-ordinating a forced expiration.

SEVERITY AND PRIOR DIAGNOSIS OF COPD

Of the 57 patients with COPD, 30 (53%) had mild, 15 (26%) had moderate and 12 (21%) had severe disease by BTS criteria. Twenty-three patients (40%) had a diagnosis of COPD prior to the study. Patients with a prior diagnosis were more likely to have severe (eight of 12 patients) rather than moderate (eight of 15) or mild (seven of 30) disease ($\chi^2 = 3.9, P < 0.05$).

QUALITY OF LIFE SCORES

There were significant differences in quality of life scores between patients with normal lung function and COPD (Fig. 1). This held for total and component scores (total, mean difference $= 11.5, P < 0.01$; impact $= 10.0, P < 0.05$; symptoms $= 12.6, P < 0.01$; and activity $= 13.9, P < 0.01$). Differences in scores for patients with asthma compared to those with normal lung function and with COPD were not significant.

For patients with COPD, quality of life scores were worse for those with severe disease compared with those with mild and moderate COPD (total, mean difference $= 15.8, P < 0.05$; impact $= 19.0, P < 0.01$; symptoms $= 13.9, P = n.s.$; activity $= 11.1, P = n.s.$).

THE SECOND AND THIRD PRACTICE VISITS: CORTICOSTEROID TRIAL

Twenty-three of the 57 (40%) patients with COPD completed a corticosteroid trial (19 took oral prednisolone; four took inhaled corticosteroid), of which only one showed a significant spirometric response. Of the 34 patients who did not complete a trial, nine suffered exacerbations, six failed to adhere to the regimen, four began but stopped due to intercurrent illness, two were already taking oral corticosteroids, three could no longer be contacted and 10 patients declined to start a trial.

Discussion

This pragmatic study shows that spirometry by a specialist nurse was feasible in these British inner-city general practices. This technology is not yet part of routine practice in spite of its central position in recommendations of U.K.

Table 1. Demography and lung function in patients attending for bronchodilator reversibility testing (Means and SD unless otherwise stated)

<table>
<thead>
<tr>
<th></th>
<th>Normal spirometry</th>
<th>Asthma</th>
<th>COPD</th>
<th>Poor tests</th>
<th>All patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>No (%) with diagnosis</td>
<td>58 (34)</td>
<td>40 (24)</td>
<td>57 (34)</td>
<td>13 (8)</td>
<td>168</td>
</tr>
<tr>
<td>No (%) men</td>
<td>14 (24)</td>
<td>19 (48)</td>
<td>18 (32)</td>
<td>3 (23)</td>
<td>54 (32)</td>
</tr>
<tr>
<td>Age</td>
<td>64 (8)</td>
<td>67 (11)</td>
<td>69 (8)</td>
<td>72 (8)</td>
<td>67 (9)</td>
</tr>
<tr>
<td>No (%) 'never' smokers</td>
<td>23 (40)</td>
<td>8 (20)</td>
<td>9 (16)</td>
<td>5 (39)</td>
<td>45 (26)</td>
</tr>
<tr>
<td>No (%) ex smokers</td>
<td>22 (38)</td>
<td>15 (37)</td>
<td>28 (49)</td>
<td>7 (54)</td>
<td>72 (45)</td>
</tr>
<tr>
<td>No (%) current smokers</td>
<td>13 (22)</td>
<td>17 (43)</td>
<td>20 (35)</td>
<td>1 (8)</td>
<td>51 (30)</td>
</tr>
<tr>
<td>Pack years smoking</td>
<td>33-69 (34-71)</td>
<td>38-75 (29-84)</td>
<td>47-27 (27-45)</td>
<td>28-13 (26-72)</td>
<td>39-94 (30-67)</td>
</tr>
<tr>
<td>(mean and range)$^+$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pack years smoking</td>
<td>22 (1-126)</td>
<td>32-5 (1-150)</td>
<td>44 (1-114)</td>
<td>19 (5-88)</td>
<td>37 (1-150)</td>
</tr>
<tr>
<td>(median and range)$^+$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEV1 (l)</td>
<td>2-13 (0-59)</td>
<td>1-43 (0-49)</td>
<td>1-23 (0-44)</td>
<td>N/A</td>
<td>1-62 (0-65)$^*$</td>
</tr>
<tr>
<td>% predicted FEV1</td>
<td>90.88 (9.05)</td>
<td>62.88 (71.47)</td>
<td>55.79 (15.90)</td>
<td>N/A</td>
<td>70-75 (22.15)$^*$</td>
</tr>
<tr>
<td>FEV1/FVC</td>
<td>0-76 (0-08)</td>
<td>0-62 (0-13)</td>
<td>0-57 (0-13)</td>
<td>N/A</td>
<td>0-65 (0-14)$^*$</td>
</tr>
<tr>
<td>% reversibility</td>
<td>6-15 (4-38)</td>
<td>26-12 (10-95)</td>
<td>9-21 (6-55)</td>
<td>N/A</td>
<td>12-55 (11-03)$^*$</td>
</tr>
<tr>
<td>No with &gt;15% and 200 ml</td>
<td>0</td>
<td>40</td>
<td>0</td>
<td>0</td>
<td>40</td>
</tr>
</tbody>
</table>

$^*$excluding patients classified as poor tests; $^+$ ex smokers and current smokers only. FEV1: forced expiratory volume in 1 sec; FVC: forced vital capacity.
national COPD guidelines encompassing primary care management. We assessed diagnostic accuracy of older patients on asthma registers. Just over half of all patients invited took up the offer of spirometry. Assessments showed a surprising spectrum of lung function, allowing us to differentiate patients into three groups, according to British Thoracic Society definitions. New diagnoses of COPD were more likely in those with mild or moderate disease. Only one patient with COPD showed a significant response to a corticosteroid trial.

FACTORS INFLUENCING OUR RESULTS

Our sampling frame was the practice asthma register. The composition of registers will differ between practices depending on several factors, including diagnostic criteria for asthma, the mechanism used to add patients to registers, the duration of register use and the existence of any mechanism to remove patients without active disease. The third practice in this study had a higher computer recorded asthma prevalence across all age groups, reflecting earlier use of computer for clinical work and possibly higher local prevalence (12). It is possible that some patients with asthma or COPD were not on the asthma registers, however, case-finding outside the practice registers was not our objective. Although our study took place in a multicultural inner-city area, language problems prevented assessment in only six patients.

Diagnosis of asthma and COPD is a controversial area and definitions vary across Europe. We used the diagnostic criteria of the British Thoracic Society; use of other criteria might give different proportions of patients in our diagnostic categories.

PRACTICAL IMPLICATIONS FOR PRIMARY CARE

Patients with normal spirometry

The patients we categorized as having normal spirometry are almost certainly a heterogeneous group, probably comprised mostly of patients with well controlled asthma, some with inactive asthma, some with minor obstructive changes and some without lung disease. For example, one patient in this group was later found to have breathlessness secondary to heart failure. Further study of these patients could differentiate between these subgroups.

Patients with asthma

We confirmed a diagnosis of asthma in roughly one third of patients. This may be a slight under-estimate since, as noted above, some patients with normal spirometry may have had well controlled asthma. Spirometry may provide a useful baseline from which to monitor treatment changes or deterioration in lung function over time. Some may progress to fulfill criteria for COPD as their lung function deteriorates with time. This effect may account for some
apparent disease misclassification since patients may have been placed on registers many years previously.

**Patients with COPD**

One third of patients had irreversible obstruction. Our decision not to apply the BTS criterion of an FEV1/FVC ratio of <70% resulted in the inclusion of only two patients with restrictive defects in the COPD group. Only one of 23 (4%) COPD patients showed a significant response to a corticosteroid trial. This is within the range (0-38%, mean 10%) found in a meta-analysis of 15 studies of spirometric response to corticosteroids in patients with stable COPD (13).

**Should COPD patients without a corticosteroid response stop inhaled steroids?**

The place of inhaled steroids for patients with COPD is uncertain (14,15). Bourbeau found no physiological or functional benefit of 6 months inhaled corticosteroid in patients with severe COPD, suggesting that failure to respond to oral corticosteroids selects patients unlikely to respond to inhaled corticosteroid (16). Early results of the EUROSCOP study (17) suggest that inhaled corticosteroids have a small and brief effect on deterioration of lung function of patients with mild COPD; results from the ISOLDE study (18) (addressing severe COPD) are awaited. Whilst inhaled corticosteroids do not prevent COPD exacerbations, they may ameliorate them (19). Whilst Barnes recommends a trial of high dose inhaled corticosteroids in COPD patients (20), a more practical approach (since most are already on this treatment) is to stop inhaled corticosteroids and monitor for any changes in FEV1 and exacerbation rates. Benefits for patients stopping inhaled corticosteroids are simplification of complex inhaler regimes and avoidance of potential adverse effects. Assuming the misclassification rate found in this study can be generalized to other general practices, a further benefit may be considerable savings in National Health Service drug budgets.

**Identifying patients with new diagnoses of COPD in primary care**

Most of the patients with new diagnoses of COPD had mild or moderate disease. Whilst those with severe disease are clearly the most important to identify, earlier diagnosis in primary care of mild and moderate COPD will allow targeting of smoking cessation advice and the offer of other management options.

**Quality of life measurements**

Quality of life measurements provided a useful additional assessment of disability in this study: they confirmed that even patients with mild and moderate COPD had impaired quality of life. Disability relates not only to lung function but also to factors such as exacerbation rates (21) and coping skills. (22) General practitioners are being encouraged to incorporate quality of life measurement into routine care: a brief, practical and responsive tool for patients with COPD is needed.

**Is spirometry feasible in primary care?**

We found spirometry feasible in these practices. Approximately one in five patients declined spirometry and a similar proportion could not be contacted. Those that took part found assessments acceptable and most COPD patients agreed to a corticosteroid trial. Practice nurses were enthusiastic about using spirometry, and general practitioners welcomed more rational diagnosis and management of a difficult group of patients. However, several issues are unresolved in the use of spirometry in primary care. Firstly, skills and experience in performing and interpreting spirometry are needed. Specialist respiratory nurses need to support practices in starting a service and provide additional practice nurse training. Costs to practices in staff-time and equipment may need to be met directly. Secondly, many practices, especially those without a practice nurse, may find referral to a specialist clinic a more realistic option. U.K. Primary Care Groups will need to contract for direct access for spirometry for such practices, and support and training for those wishing to carry out their own. Advantages for practices using spirometers will be offset by opportunity costs. Economic analyses should address this. Thirdly, quality control is important in a decentralized service; spirometers must be calibrated for reliable measurement and results from spirometers without pictorial traces are more likely to be misinterpreted. Finally, although our results suggest spirometry is useful in clarifying diagnoses, its role in guiding management decisions in primary care has been questioned and remains to be clarified (23).

**Diagnostic Categorization of Patients**

The BTS guidelines present one of several diagnostic criteria for COPD (6,24). Such criteria have limitations, particularly the separation of patients with a spectrum of disease into distinct but somewhat arbitrary categories. Nonetheless, our study demonstrates that spirometry used in primary care can highlight considerable misclassification. The promotion of a more critical approach to diagnosis of lung disease in primary care is long overdue. The use of more reproducible and objective measures of lung function will help, provided adequate training in use and interpretation is available.

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