

Predictive value of primary care made clinical diagnosis of chronic obstructive pulmonary disease (COPD) with secondary care specialist diagnosis based on spirometry performed in a lung function laboratory

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Aim: To define the predictive value of clinical diagnosis of chronic obstructive pulmonary disease (COPD) or suspected COPD in primary care patients with spirometric criteria for diagnosis. **Background:** The diagnosis of COPD is usually made clinically but often not confirmed by diagnostic testing. Recent initiatives have called for universal spirometry testing in primary care to diagnose and monitor such patients the implications of this policy on diagnostic accuracy are not as yet known. **Methods:** Retrospective comparative analysis of 677 consecutive primary care referrals to a district general hospital lung function laboratory for spirometry, March 1998 to December 2006. **Findings:** Five hundred and three of 677 patients referred for open access spirometry had a primary care clinical diagnosis or suspected diagnosis of COPD. When compared with NICE spirometric criteria for diagnosis of COPD, 141 patients (28%) had normal spirometry, 46 (9%) had reversible airflow obstruction and 14 (3%) a restrictive pattern of spirometry. The positive predictive value of a primary care clinical diagnosis of COPD was 0.62 for patients referred for assessment of severity and 0.56 for those referred for diagnostic testing. Clinical suspicion of COPD in this sample was not confirmed by spirometry in a high proportion of referred patients. The introduction of the widespread use of spirometry for confirmation of primary care clinician made COPD diagnosis have important implications for both individual patients and primary care service planning.

Key words: COPD; diagnosis; primary care; spirometry

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Background

Inaccurate diagnosis of chronic obstructive pulmonary disease (COPD) in primary care has significant implications, both for individual patients and for service planning on a macro-scale. Published guidelines on the management of COPD state that

diagnosis must be confirmed by spirometric testing (NICE, 2004; NHLBI, 2008). The UK national guidance (NICE, 2004) is that primary care medical practitioners should have access to this diagnostic test either within their own practices or via a specialist centre such as secondary care. Not all primary care practices have their own spirometers and for those that do, there are concerns about quality assurance and interpretation of results based on the experience of primary care use of spirometers elsewhere in Europe (Schermer *et al.*,

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2003; Sichletidis *et al.*, 2007). We explored the diagnostic accuracy of primary care made clinical diagnosis of COPD with that of hospital respiratory specialists based on spirometry data in patients referred by their general practitioners to an open access service lung function laboratory service.

Methods

A retrospective analysis was performed of all primary care referrals for spirometry to a hospital lung function laboratory between March 1998 and December 2005. The request form included patient details, the indication for testing and a clinical diagnosis. Details of spirometry on all consecutive referrals were recorded on an Excel (Microsoft Inc.) database. The primary care clinical diagnosis or suspected diagnosis was compared with the spirometry results as interpreted by a secondary care respiratory specialist. Spirometry was performed by a qualified technician according to ERS/ATS criteria (Brusasco *et al.*, 2005). Either a Jaeger Masterscreen Pneumotac spirometer (Viasys, Warwick, UK) or a Morgan Benchmark (Ferraris PK Morgan Ltd., Cardiff, UK) volume displacement spirometer was used.

The following were recorded for each patient: primary care clinical diagnosis, age, sex, height, weight, spirometry test measurements, secondary care specialist reported diagnosis based on spirometry results.

Where primary care clinicians requested spirometry followed by bronchodilator administration to assess reversibility additional values were recorded for pre-bronchodilator administration (pre.) and post bronchodilator administration (post.). A standard dose of 400 µg salbutamol was administered via a spacing device and spirometry repeated 20 min later.

Patients were grouped into one of three main spirometric diagnostic categories:

- Normal ($FEV_1 \geq 80\%$ and FEV_1/FVC ratio $\geq 70\%$)
- Reversible airflow obstruction suggestive of asthma (baseline $FEV_1 < 80\%$ and FEV_1/FVC ratio $< 70\%$ with >400 mL and $>15\%$ baseline improvement in FEV_1 following bronchodilator administration).
- Airflow obstruction possible asthma possible COPD (FEV_1/FVC ratio $< 70\%$ and $FEV_1 <$

80%) and either insignificant reversibility post bronchodilator administration or no bronchodilator administered to test reversibility.

Patients referred were further subdivided into two groups for analysis. First, those where the clinical details were of a clinical diagnosis of COPD and a request to quantify the severity of the COPD, and second, where the referring clinician was questioning a possible diagnosis of COPD most often as a differential diagnosis with asthma.

Results

Of the 677 patients referred for spirometry during the study period, 503 (74%) were referred either with a clinical diagnosis of COPD to assess severity ($n = 326$) or with a suspected diagnosis of COPD, for diagnostic testing ($n = 177$). For the remaining patients, the primary care diagnoses were possible asthma, cough, shortness of breath unknown cause, pre-operative assessment, possible bronchiectasis, previous history of TB, or no information given on the request form. Only the 503 subjects with a diagnosis of COPD or possible COPD are considered further.

Of these 503 patients, 280 (56%) had spirometry both before and after bronchodilator administration to assess reversibility. Two hundred and sixty-two of the 503 patients (50.2%) were male. Spirometry results for these 503 are given in Table 1.

One hundred and forty-one of the 503 patients (28%) tested had measured spirometry within normal limits. A further 14 patients (3%) demonstrated a restrictive defect (mostly associated with a high body mass index). Of the remaining patients, 46/503 (9%) had airflow obstruction but a significant bronchodilator response (>400 mL and $>15\%$ increase in FEV_1), and as such were classified as asthma even though they may or may not have a degree of co-existent COPD. The remaining 302/503 (60%) patients from the group did have significant airflow obstruction measured by spirometry and either did not receive bronchodilators or had a non-significant response to bronchodilators at the time of testing. For the purposes of this study these patients were classified as having probable COPD. This group of patients was, however, recommended to undergo serial peak flow readings at home. It is

Table 1 Spirometry data from 503 subjects tested with a primary care made diagnosis of either COPD or possible COPD

| | Age (years) | FEV ₁ (l) | | % Pred. FEV ₁ | Ratio of | | FVC (l) | | % Pred. FVC |
|------|-------------|----------------------|-----------------------|--------------------------|----------|----------|---------|----------|-------------|
| | | Pre. BD (n = 503) | Post. BD (n = 280) | | Pre. BD | Post. BD | Pre. BD | Post. BD | |
| Mean | 63.8 | 1.83 | 1.79 | 73.37 | 61.2 | 57.5 | 2.94 | 3.07 | 93.5 |
| SD | 11.3 | 0.89 | 0.87 | 28.52 | 15.6 | 14.2 | 1.07 | 1.06 | 23.4 |

Pre. BD = pre bronchodilator administration; post. BD = post bronchodilator administration.

Table 2 Analysis of positive predictive value of clinical diagnosis of COPD or possible COPD compared with measured spirometry criteria

| Referral diagnosis | Spirometry compatible | Spirometry incompatible | Positive predictive value |
|-----------------------------------|-----------------------|-------------------------|---------------------------|
| COPD to assess severity (n = 326) | 203 | 123 | 0.62 |
| Possible COPD (n = 177) | 99 | 78 | 0.56 |
| All cases (n = 503) | 302 | 201 | 0.6 |

likely that some will have demonstrated significant reversibility, although we were not able to follow up these patients to final diagnosis.

Patients were further analysed according to the specific primary care question asked. One group of patients was referred as clinical diagnosis of COPD for spirometry assessment of the severity of their disease and the second group was patients with a suspected diagnosis of COPD referred for spirometry to confirm or refute this. A summary of results for these groups separated and combined is given in Table 2 with the positive predictive value of a primary care made clinical diagnosis compared with the spirometry diagnosis.

Discussion

In this study, we have demonstrated that 40% of patients with a primary care made clinical diagnosis or suspected diagnosis of COPD referred for open access testing have spirometry results incompatible with a diagnosis of COPD. Even when patients referred for diagnostic testing where the diagnosis by implication is uncertain are excluded, the diagnostic accuracy in patients with an assumed diagnosis is little better (Table 2). This finding has significant implications both for individual patients and in the wider context of service planning and delivery. An individual patient misdiagnosed clinically with

COPD on the basis of the symptom of breathlessness in a smoker or ex-smoker not only risks being placed on inappropriate medications for a condition they do not have but also faces a delayed appropriate diagnosis. On a larger scale service planning and resource allocation for the management of COPD based on clinical diagnosis alone risks significant miscalculation with inappropriate allocation of resources. This, coupled with the evidence that many patients with genuine COPD remain undiagnosed by clinical means alone (Dales *et al.*, 2006; Vandevorde, 2007), suggests that the widespread implementation of spirometry within primary care will have a major impact on costs and service provision in the community that deserves future detailed study.

Our findings are not dissimilar to those of Wolfenden *et al.* (2006) who studied a smaller referral population. The diagnostic accuracy in that study was similar with 53% of patients referred with suspected COPD having spirometry-confirmed airflow obstruction. In that study a higher proportion (14.5%) was observed with restrictive disorders. These differences are likely to represent the distinct characteristics of the two referral populations but provide similar conclusions about the diagnostic accuracy of a primary care clinical diagnosis of COPD.

It is important to acknowledge the diagnostic limitations of a single time point measurement of airflow obstruction. Whilst a measurement within

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normal limits excludes a diagnosis of COPD, it does not exclude a diagnosis of asthma. Equally, demonstration of spirometric airflow obstruction may indicate COPD but cannot exclude a reversible component (asthma). A positive response to bronchodilators may help in distinguishing these conditions but once again a non-significant response does not rule out reversibility at other times (NICE, 2004). We observed a relatively small percentage of patients with suspected COPD demonstrating bronchodilator reversibility. In a primary care setting, it may be more useful to perform serial peak flow monitoring in all those who demonstrated airflow obstruction. In this study it is possible that we have slightly over- or underestimated the prevalence of COPD in our sample. Some of these patients with spirometry-proven airflow obstruction will have variability and reversibility if subjected to serial monitoring and therapeutic trials whilst some with demonstrated reversibility will have concomitant COPD. These observations highlight the need for spirometry data to be considered in conjunction with clinical information and other physiological tests such as peak flow and spirometry-based reversibility studies (Walker *et al.*, 2006).

The recommendation that spirometry should be available to all primary care clinicians managing COPD cases is supported by our data. Within the UK the move has been very much towards the provision of spirometry in general practice premises. There are, however, significant difficulties still to overcome if this approach is universally adopted. Technical accuracy of spirometry is not as quality assured in general practice as in hospital settings when performed by qualified technicians (Akhtar and Wilson, 2005). General practice doctors themselves may also lack confidence in interpreting the results (Bolton *et al.*, 2005). It would be a false reassurance to provide spirometers in every practice if the quality of both the measurement and the interpretation led to further diagnostic inaccuracies. The open access secondary care model illustrated in this study provides solutions to both these issues by using trained technicians to perform testing with specialist physicians reporting the results. Such a model is, however, very much against the current movement of care into the community and the research base from Poland and Australia provides an alternative model where spirometry experts

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can improve quality and accuracy of primary care diagnosis of COPD by providing near-site testing in surgeries (Bednarek *et al.*, 2008; Walters *et al.*, 2008). It seems unlikely that quality and diagnostic accuracy of spirometry performed by UK general practitioners and practice nurses will be significantly different from that found in other national quality data studies but it may be that future UK-based research is required before the call for the provision of spirometry and not spirometers to general practice (Enright, 2008) will be heeded by the commissioners of service.

In summary we have reaffirmed in a large cohort of patients that the clinical diagnosis of COPD in primary care is frequently inaccurate when compared against a respiratory specialist made diagnosis based on spirometry. Bronchodilator reversibility testing provided little further information in the majority of patients. There are significant implications for both individual patients and service planning. The implementation of universal access to spirometry across general practice should reduce the likelihood of a false-positive diagnosis in patients presenting with suspected COPD and increase the detection of previously undiagnosed cases. Open access secondary care-led spirometry or near-patient testing delivered by trained experts in lung function testing offers a service with quality-assured technical performance and expert clinical interpretation of results that challenges the current concept of an entirely internally provided general practice service.

Conflicts of interest: The authors declare no conflicts of interest.

Ethics statement: Formal ethics approval not required for this retrospective analysis of clinical service data as advised by the UK National ethics research service.

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