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ORIGINAL RESEARCH

A comparison of spirometry in general practice and a pulmonary function laboratory

Rashed Akhtar, Andrew Wilson*

Department of Health Sciences, Division of General Practice & Primary Health Care, University of Leicester, Leicester General Hospital, Leicester LE5 4PW, UK

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Summary
Aims: To compare the results of spirometry testing in primary care with those obtained at a pulmonary function laboratory and to explore whether differences were due to technique or equipment.
Methods: Patients on the waiting list for spirometry in six participating practices had the test performed in their own practice and at the pulmonary function laboratory (PFL).
Results: A total of 45 patients had spirometry performed at both locations. Practice nurses underestimated FEV_1 and FVC. The mean difference in FEV_1 was 0.109 litres (6.69%, 95% CI 2.88, 9.51) compared with a bellows spirometer, and 0.07 litres (6.2% 95% CI 0.89, 8.25) when the same type of spirometer was used. The mean difference in FVC was 0.413 litres (15.0% 95% CI 9.3, 20.6) when compared with bellows, and 0.267 litres (10.2% 95% CI 4.1, 16.2) when the same type of spirometer was used. All differences were statistically significant ($p < 0.05$, paired t test). Agreement on categorization of COPD was moderate (Kappa 0.46) with practice nurses overestimating severity. Compared to PFL categorisation for the presence or absence of COPD using bellows spirometers, the sensitivity of practice nurse spirometry was 0.93 (95% CI: 0.76, 0.99) and specificity 0.65 (95% CI: 0.38, 0.86).
Conclusion: Spirometry results obtained by practice nurses were lower than those obtained in a PFL, leading to over-diagnosis of COPD severity.

Introduction

The importance of spirometry in diagnosing chronic obstructive pulmonary disease (COPD) in general practice has recently been emphasised [1,2]. In the UK the number of practices offering this procedure is increasing in response to the new General

* Corresponding author. Tel.: +44 116 258 4367; fax: +44 116 258 4982.
E-mail address: aw7@le.ac.uk (A. Wilson).

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Medical Services (GMS) contract, which sets targets for the proportion of COPD patients who have had their diagnosis confirmed by spirometry [3]. There is debate about whether the best approach to meeting the need for spirometry is to train practice nurses who can perform this procedure in the practice, or whether to develop open access, hospital-based services. In a recent UK survey, only 11% of GPs had open access to spirometry services, whereas 60% reported that they would use this resource if available [4]. GPs seem to prefer to use hospital spirometry rather than a practice-based service, even in those practices which have a spirometer [5,6].

One reason for this preference is concern about the accuracy of spirometry in general practice. These relate to both the training and monitoring of nurses performing spirometry and the calibration of equipment. Two studies, in the Netherlands and Spain respectively, have suggested that greater accuracy is obtained in pulmonary function laboratories than in primary care [7,8], and a study in New Zealand found that a training package had only modest results [9].

Spirometers can measure volume displacement directly (eg a bellows device) or derive volume from the sensing of flow (eg Fleisch-type vitalograph) [10]. Pressure transducers are the devices of choice in primary care because of their affordability, portability and ease of use. However, some models lack accuracy and produce a hard copy print-out only when used in conjunction with a computer. Studies have shown that different spirometers may agree poorly with one another, and as a result their measurements may not be comparable [11,12].

This study aimed to compare the results of spirometry testing in primary care with those obtained with the same patients in a pulmonary function laboratory. A secondary aim was to explore whether any differences could be explained by differences in technique or equipment.

Method

Practice nurses in six practices in Leicestershire known to have an interest in spirometry agreed to take part. Each was asked to invite ten patients, who were due to have spirometry performed in the practice either as a diagnostic test or for monitoring of COPD, to take part. Patients who consented were then given appointments to have spirometry performed both at the practice and at the pulmonary function laboratory (PFL) at Glenfield General Hospital within one month of each other, with the sequence of testing randomised. Patients with unstable COPD and those unable to travel to hospital were excluded. Practices used their usual spirometers. At the PFL, patients were tested using a bellows device and then the same type of spirometer as the practice, in that order. All practices used pressure transducers.

One of the authors (RA) attended both spirometry tests and assessed the operator's spirometry technique using a checklist of mandatory criteria derived from British Thoracic Society Guidelines (see appendix A) with each criterion scored as being present or absent [13]. At the end of the study participating practice nurses were asked to complete a short questionnaire on their training and frequency of spirometry testing.

After patient tests were completed, spirometers in the practices were tested for accuracy using the *Multiflow* 3-litre volume calibration syringe, produced by Pulmonary Data Service Instrumentation, 908 Main Street, Louisville, CO 80027. Three litres of air were pumped through the spirometer at 0.5, 1.0, 2.0 and 3.0 litres/s and the FVC was recorded at the different flow rates. This was compared to the manufacturers' specifications for accuracy.

Spirometry results from general practice and the PFL were compared. Continuous data (height, FVC, FEV_1) were compared using paired *t* tests and mean percentage differences calculated. Differences between nurses were explored using Bland Altman plots [14]. Severity of COPD was categorized as normal, mild, moderate or severe according to British Thoracic Society guidelines [13], and agreement calculated using a weighted kappa (κ) statistic [15].

The study aimed to find a difference of 10% in continuous variables, which was judged to be clinically important, using an estimate of the standard deviation of the differences. For 80% power to detect such a difference, 33 subjects would be needed. This figure was inflated to 60 (6 nurses each recruiting 10 patients) to account for unknown variations between nurses.

Results

Fifty-three patients were recruited but only 45 had tests at both locations. Of these 29 were seen first at the practice and 16 at the PFL. This difference was explained by a higher drop out rate in patients randomised to attending the PFL first. The mean

Table 1 Height, FEV_1 and FVC recorded in primary care (PC) and pulmonary function laboratory (PFL) using bellows spirometers and the same spirometer used in primary care (comparison).

	Mean	N	Std. deviation (S.D.)	Std. error mean (S.E.M.)	Correlation	Sig.
Height (cm) PC	167.3	44	10.81	1.63	0.940	.000
PFL	165.7	44	9.50	1.43		
FEV_1 (l) PC	1.53	45	0.8311	0.1239	0.978	.000
PFL bellows	1.63	45	0.8617	0.1285		
PC	1.53	45	0.8311	0.1239	0.972	.000
PFL comparison	1.60	45	0.8177	0.1219		
FVC (l) PC	2.35	45	1.0418	0.1553	0.872	.000
PFL bellows	2.76	45	0.9974	0.1487		
PC	2.35	45	1.0418	0.1553	0.864	.000
PFL comparison	2.61	45	0.9311	0.1388		

age of the sample was 66.3 years (SD 9.84), 27 patients (50.1%) were female, and all patients were white European. The number of patients tested by each of the six practice nurses were 4, 7 (two nurses), 8, 9 and 10.

Height, FEV_1 and FVC

Results are shown in Tables 1 and 2. All comparisons of continuous data showed statistically significant differences. Practice nurses overestimated height by an average of 1.64 cm (1.0%). There was underestimation of FEV_1: mean difference was 0.109 (6.7%) compared with bellows and 0.07 (6.2%) when the same type of spirometer was used. Differences in FVC were greater: mean difference 0.413 (15.0%) when compared with bellows and 0.267 (10.2%) when the same type of spirometer was used. Bland-Altman plots [14] did not suggest any systematic variation between nurses, although numbers were too small for statistical analysis.

Classification of COPD

Table 3 compares clinical diagnosis of COPD in primary care compared with bellows and comparison spirometry in PFL. Both comparisons gave very similar results with Kappa statistics of about 0.46, indicating 'moderate' agreement [15]. When classification was dichotomized into presence or absence of disease, the sensitivity of practice nurse spirometry was 0.93 with specificities of 0.65 and 0.69 for bellows and comparison spirometers respectively.

Comparison of spirometry technique

The total scores (out of a maximum 20) for meeting checklist criteria for the 45 patients seen in both settings were compared. Median (IQR) score for

Table 2 Differences in Height, FEV_1 and FVC recorded in primary care (PC) and pulmonary function laboratory (PFL) using bellows spirometers and the same spirometer used in primary care (comparison).

Paired differences								
	Mean (%)	Std. deviation (S.D.)	Std. error mean (S.E.M.)	95% Confidence interval of the difference (%)		*t*	D.f.	Sig. (2-tailed)
				Lower	Upper			
Height (cm)								
PC − PFL	1.64 (0.99)	3.74	0.560	0.500 (0.30)	2.77 (1.67)	2.91	43	.006
FEV_1 (litres)								
PC − bellows	−0.109 (6.69)	0.180	0.0268	−0.155 (9.51)	−0.0469 (2.88)	−3.76	44	.000
PC − comparison	−0.0733 (6.20)	0.197	0.0293	−0.132 (8.25)	−0.0143 (0.89)	−2.50	44	.016
FVC (litres)								
PC − bellows	−0.413 (15.0)	0.517	0.0771	−0.569 (20.6)	−0.258 (9.3)	−5.36	44	.000
PC − comparison	−0.267 (10.2)	0.526	0.0784	−0.422 (16.2)	−0.106 (4.1)	−3.36	44	.002

Table 3 Comparison of COPD severity assessed in primary care with assessment in PFL using bellows and comparison spirometers.

	PFL bellows spirometer				
	None	Mild	Moderate	Severe	Total
Kappa 0.459[a]					
Primary care					
None	11	1	1		13
Mild	4	4	1	1	10
Moderate	2	2	7	1	12
Severe			5	5	10
Total	17	7	14	7	45
	PFL comparison spirometer				
	None	Mild	Moderate	Severe	Total
Kappa 0.460[b]					
Primary care					
None	11	1	1		13
Mild	3	4	2	1	10
Moderate	2	3	6	1	12
Severe			4	6	10
Total	16	8	13	8	45

[a] Sensitivity in detecting all grades of COPD 26/28, 0.93 (95% CI: 0.76, 0.99). Specificity in detecting all grades of COPD 11/17, 0.65 (95% CI: 0.38, 0.86).
[b] Sensitivity in detecting all grades of COPD 26/28, 0.93 (95% CI: 0.76, 0.99). Specificity in detecting all grades of COPD 11/16, 0.69 (95% CI: 0.41, 0.89).

practice nurses was 18 (16.5, 19.5) compared with 20 (18, 20) for PFL technicians ($p = 0.03$ Wilcoxon test). Criteria with the biggest differences were: attaining plateau readings (62% patients with practice nurse, 84% patients with technicians); obtaining full exhalation (82% versus 98%); and encouragement (82% versus 100%).

Practice nurse training and experience

At the end of the study five of the six practice nurses completed a short questionnaire. Results showed that all had received training outside the practice between one and five years ago, but in only one case was the course formally certified. Most performed spirometric testing at least weekly and all at least monthly.

Spirometer accuracy

The spirometers used in general practice were tested for accuracy at the end of the study. The average value of FVC when 3 litres of air was injected at different rates is shown in Table 4. Only one spirometer measured 3.0 litres of air to within 0.1 litres of accuracy across the range of flow rates. The range of inaccuracy was from 2.82 to 3.15 litres.

Table 4 Practice spirometer readings for 3 litres of air pumped at different flow rates (average of three readings).

Practice number	FVC (l)				
	0.5 l/s	1.0 l/s	2.0 l/s	3.0 l/s	Model
1	2.83	2.98	2.96	3.01	Micro Lab 3500
2	2.82	2.90	2.99	3.02	Micro Lab 3500
3	3.13	3.19	3.07	3.11	Micro plus
4	3.01	3.00	3.05	3.06	Micro Lab 3300
5	3.03	3.02	3.16	3.16	Micro Lab 3300
6	2.99	2.95	3.04	3.10	Micro Lab 3300

Discussion

Summary of findings

The results of this study show clearly that, on the same patients, practice nurses obtain lower values for FEV_1 and FVC than do technicians in a PFL. These findings are essentially unchanged whether the comparison is with a bellows instrument or the same type of spirometer as was used in practice. One reason for lower readings is our finding that practice nurses use less encouragement to the patient to achieve full expiration, an explanation supported by greater differences in FVC than FEV_1, and consistent with other studies [9].

The finding that practice nurses record greater heights than PFL technicians was surprising, but could be because height is recorded in the general practice notes, and may be self-reported rather than by measurement. This source of error clearly contributed to over diagnosis of COPD and its severity.

This study was conducted with volunteer practices known to have an interest in spirometry. At least five of the six participating nurses had received external training in the technique and performed the test regularly. Furthermore, they were observed during the study and so were likely to maximise their effort to perform well. It therefore seems very likely that a comparison with a more representative group of practice nurses would show greater differences in FEV_1 and FVC values between general practice and PFL than were seen here.

Limitations

We included 45 paired readings, short of our projected sample size of 60, which was itself calculated in the absence of any literature on practice nurse variation that would allow us to estimate clustering effects. Our analysis has not taken account of clustering as we do not feel that with such small numbers this would be meaningful. This omission may have led to overestimates of statistical significance. Because those randomised to PFL spirometry first were more likely to drop out, we included more patients who saw the practice nurse first. This could mean that some of the higher readings obtained in the PFL were due to a learning effect. The sequencing of testing in the PFL could explain the slightly lower readings obtained from pressure transducers, because of the effect of fatigue after the test using bellows. Another assumption was that participating patients' condition was stable between the two tests; normal variation could explain some of the lack of sensitivity and specificity in diagnosing COPD. Finally there was potential for observer bias in assessing operator techniques, but given the study design, blinding was not possible. The normal protocol for patients performing spirometry is that they should not use inhaled medication eight hours prior to the test. However, participating patients were not notified of this requirement. Some patients used inhalers at one appointment and not the other, thus making comparisons less valid, but we have no evidence that this occurred more frequently at either location.

Implications and comparison to existing research

The study suggests that, as in other countries [7–9] spirometry conducted in UK general practice has some limitations compared with a hospital-based test. Some of the problems we have identified, especially the need to verify height objectively, are easily remedied; others, such as the operator actively encouraging the patient, could be addressed through ongoing training and quality control. It is inevitable that some differences in performance between practice nurses and PFL technicians will persist, if only because the latter perform spirometry so much more frequently. A larger study is needed to see whether these differences are important clinically, and to compare strategies using practice- and hospital-based spirometry, including a health economics appraisal and patient preferences.

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Appendix A. Criteria for conducting spirometry

- Calibration of equipment if necessary
- Ensuring patient is comfortable and seated
- Explanation of the purpose of the test
- Limiting the number of practice attempts to eight
- Record of sex

- Record of age
- Record of height
- Record of ethnic background
- Attaching a clean disposable mouthpiece
- Patient taking a full inspiration
- Patient sealing lips around mouthpiece
- Patient breathing out forcibly until no air left to expel
- Allowing up to 15 s or until a clear plateau has been reached
- Encouraging the patient
- Accepting only those traces free from irregularities

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