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ORIGINAL RESEARCH

Spirometry expert support in family practice: a cluster-randomised trial

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Abstract

Aim: To assess the impact of two modes of spirometry expert support on Family physicians' (FPs') diagnoses and planned management in patients with apparent respiratory disease.

Method: A cluster-randomised trial was performed with family practices as the unit of randomisation. FPs from 44 family practices recorded their diagnosis and planned management before and after spirometry for 868 patients. Intervention consisted of spirometry interpretation support by either a chest physician or expert software. Both interventions were compared with usual care (i.e. no additional interpretation support). Change in FPs' diagnoses after spirometry served as the primary outcome. Secondary outcomes were referral rate, additional diagnostic tests, and disease management changes. Effects were expressed as percentages and Odds Ratios (OR) with 95% confidence intervals.

Results: Diagnoses changed after intervention in all groups: 47.8% (95% CI 41.8 to 53.9) for chest physician support; 45.0% (95% CI 39.5 to 50.6) for software support; and 53.3% (95% CI 47.2 to 59.4) for usual care. Differences in the proportions of changed diagnosis were not statistically significant: chest physician support versus usual care OR 0.79 (95%CI 0.49 to 1.30); software support versus usual care OR 0.72 (95% CI 0.45 - 1.15). There were no differences in secondary outcomes.

Conclusion: Neither chest physician spirometry support nor expert software spirometry support had a significant impact on FPs' diagnosis of respiratory conditions or management decisions.

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See linked editorial by Jenkins on pg 128

Introduction

Although guidelines for chronic obstructive pulmonary disease (COPD) stress the central role of spirometry in diagnosing and managing chronic airways disease,[1,2] spirometry is still underused in primary care despite increased accessibility.[3,4] The most common barriers impeding utilisation of spirometry in Family practitioners' (FPs') practices are the absence of properly trained staff,[5] the lack of practice support

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to fit spirometry into the daily practice routine,[6] the absence of a spirometer in the practice,[7] and the FP's uncertainty about his or her test interpretation.[8,9] Theoretically, the latter barrier could be overcome by providing effective specialist expertise (expert support) for spirometry interpretation, either by teleconsulting a chest physician or by using a software expert support system.[10]

Although FPs welcome both kinds of expert support,[11,12] they might value support from a chest physician more than from software, because chest physicians may act as coaches for their local FPs through specific feedback for specific patients – a role computer software cannot fulfil. We have recently reported the impact of software expert support on the accuracy of FPs' diagnoses in a simulated setting.[13] However, empirical studies in a clinical setting on the effect of chest physician support or software expert support are not available.

In this study, the impact of two modes of spirometry expert support on FPs' diagnoses and planned management was assessed.

Methods

Study design

This study was a cluster-randomised trial with family practices as the unit of randomisation.

First we invited 181 family practices in three postal code regions to participate in the study by a postal mailing via the user groups of two specific patient record systems. We invited practice staff from practices who agreed to participate in the study for a 4-hour baseline spirometry workshop which was developed and pre-tested before the study.[14] This workshop included both practical instructions on how to perform high quality spirometry and how to interpret the results. Next, we equipped all practices with a spirometer (Microloop II® or Microplus®, Micro Medical/Cardinal Health Ltd, Rochester, UK).[10]

Subsequently we extracted a list of patients – for whom spirometry was important to confirm or exclude airflow obstruction[2,15] – from the practices' patient record systems based on ICPC codes R95 for COPD and R96 for asthma (i.e. patients with respiratory disease).[16] In addition, Anatomical Therapeutic Chemical (ATC) codes[17] for short-acting bronchodilators, long-acting bronchodilators, inhaled steroids, anticholinergic agents, and oral mucolytics were used to identify patients with two or more prescriptions in the last year (i.e. patients with apparent chronic respiratory disease). From each practice's combined ICPC and ATC list of patients we took a random sample (n=40) of all patients aged >30 years. The sample was weighted to reflect the proportions of patients with respiratory disease (e.g. asthma or COPD) for revision of the current diagnosis, and patients with apparent respiratory disease for assessing a new diagnosis. We excluded patients if they were primarily treated by a chest physician, had moved out of the practice, or had died. In these cases the next patient on the random selection list was included.

We then randomly allocated practices to one of the three groups: 1) chest physician support; 2) software expert support; and 3) usual care.

The FPs recorded their diagnosis and planned management before spirometry for the (randomised sample) patients on a standard form. FPs sent the completed forms to the investigators. Subsequently, selected patients performed a spirometry test either during a regular consultation or during separate office hours at the FP's invitation. We instructed practice staff to measure forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC) until three acceptable and reproducible recordings (with a <5% difference) were obtained. If the FEV_1/FVC ratio was below 0.7 practices were instructed to perform a reversibility test. Reasons for patients not attending the spirometry test were recorded by the FPs.

Intervention consisted of spirometry interpretation support by either a chest physician or expert software (see below for more detail regarding the interventions). Both interventions were compared with usual care (i.e. no additional interpretation support). FPs recorded their diagnosis and planned management after spirometry and sent the completed forms back to us.

Interventions

The intervention pertained to the cluster level (i.e. all the FPs in a particular practice).

The chest physician support group was equipped with standard spirometry software (Spida5®, Micro Medical Ltd, Rochester, UK).[10] FPs in this group used a printout of the spirometric test results (i.e. FEV_1, FVC, FEV_1/FVC, MEF_{50}, flow/volume curve) to communicate with a chest-physician by facsimile. Standard forms were used for the mutual exchange of information between FPs and chest physicians.

The software expert support group was equipped with a software-based expert system (SpidaXpert®, Micro Medical Ltd, Rochester, UK)[10] that contains a diagnostic algorithm based on pre- and post-bronchodilator FEV_1 and FEV_1/FVC values, predicted values, and their lower limits of normal for age, sex, and height. The results are presented using coloured bars that display the pre- and post-bronchodilator values of FEV_1 and FEV_1/FVC relative to the 95% confidence limits, accompanied by a textual interpretation.[10]

The usual care group was equipped with standard spirometry software (Spida5®, Micro Medical Ltd, Rochester, UK).[10] FPs in this group did not receive any additional support for the interpretation of spirometric test results.

Randomisation

Restricted computerised randomisation (minimisation) was applied (by RA) using three stratification factors: region (three postal code regions); the FP's prior experience with spirometry (< 4 or > 4 years); and the proportion of patients with respiratory disease receiving repeat prescriptions over the total number of patients receiving repeated respiratory prescriptions (<50% or > 50%) in a practice. The researchers and the statistician (RA) were blinded during the analysis and when writing the results of the paper.

Primary and secondary outcomes

A change of diagnosis (dichotomised as yes/no) in an individual patient after intervention at the FP level served as the primary study outcome. The same FPs recorded their diagnoses twice (before and after intervention) on a standardised assessment form which comprised eight pre-printed diagnostic categories;[15] asthma, asthma with persistent obstruction, COPD, restrictive lung disease, diffusive ventilatory defect, heart failure, other respiratory disease, and no respiratory disease. FPs could record a maximum of three diagnoses before as well as after reconsidering the patient's diagnosis after spirometry expert intervention (if applicable). To lower FPs' awareness of the prior diagnosis when assessing post-spirometry, FPs received their second standard assessment form for a particular patient only when they had returned the first form for that patient and when they had completed spirometry testing. When there was one diagnosis before and a different diagnosis after intervention, change of diagnosis was defined if the content of the diagnosis before and after spirometry was not the same. In cases when an FP recorded two or three diagnoses before and the same number of diagnoses after the intervention we decided on a change of diagnosis if the recorded sets of diagnoses before and after intervention were not exactly concordant.

Four secondary outcome measures were assessed: 1) referral rate; 2) ordering of additional diagnostic tests; (3) changes in respiratory medication (i.e., use of short-acting bronchodilators and/or long-acting bronchodilators and/or inhaled steroids before diagnosis and after intervention was not the same); and 4) the FP's perception of the influence of expert support on their interpretation of spirometry results (self-scored on a 5 point scale [1=no influence at all, 5=very strong influence]).

A separate study with the software expert system was conducted to assess FPs' diagnostic accuracy in a limited number of well-documented respiratory patients from family practice.[13]

Sample size

Calculation of the sample size was based on an estimated relevant 15% change in diagnosis between one of the supported groups and the usual care group. Assuming that 15% of diagnoses in the usual care group would change on reassessment of the diagnosis with new input from the spirometry test result, and assuming a 30% rate of changed diagnoses in each of the supported groups, an average of 20 patients per practice from 39 practices (13 per group) needed to be included in the study ($\alpha = 0.05$, 1β, $= 0.80$, intra-cluster correlation $r = 0.07$).

Statistical analysis

Change in diagnosis was expressed as percentage and Odds Ratios (OR) with 95% confidence intervals (95%CI) for each study group. Multilevel logistic regression analyses were performed for dichotomous variables with a random intercept model, with family practice as a random factor. Analyses were performed on an intention to treat basis (better to reflect daily practice implementation of the realistic interventions in this study) and included all patients with a diagnostic assessment by FPs before and after spirometry, regardless of actual use of expert support.

We also performed multilevel logistic regression analyses to detect possible differences between the groups in the direction of change of a diagnosis from before to after spirometry.

Finally, to detect possible effect modification, subgroup analyses were performed (Chi-square test and multilevel logistic regression analyses) for patients with respiratory disease (e.g. those with a prior diagnosis of asthma or COPD) and patients with apparent respiratory disease (who had repeatedly received prescriptions for respiratory medication without having a formal diagnosis).

Ethical approval

This study was approved by the Medical Ethics Review Board of the academic hospital Radboud University Nijmegen Medical Centre, Nijmegen, Netherlands.

Results

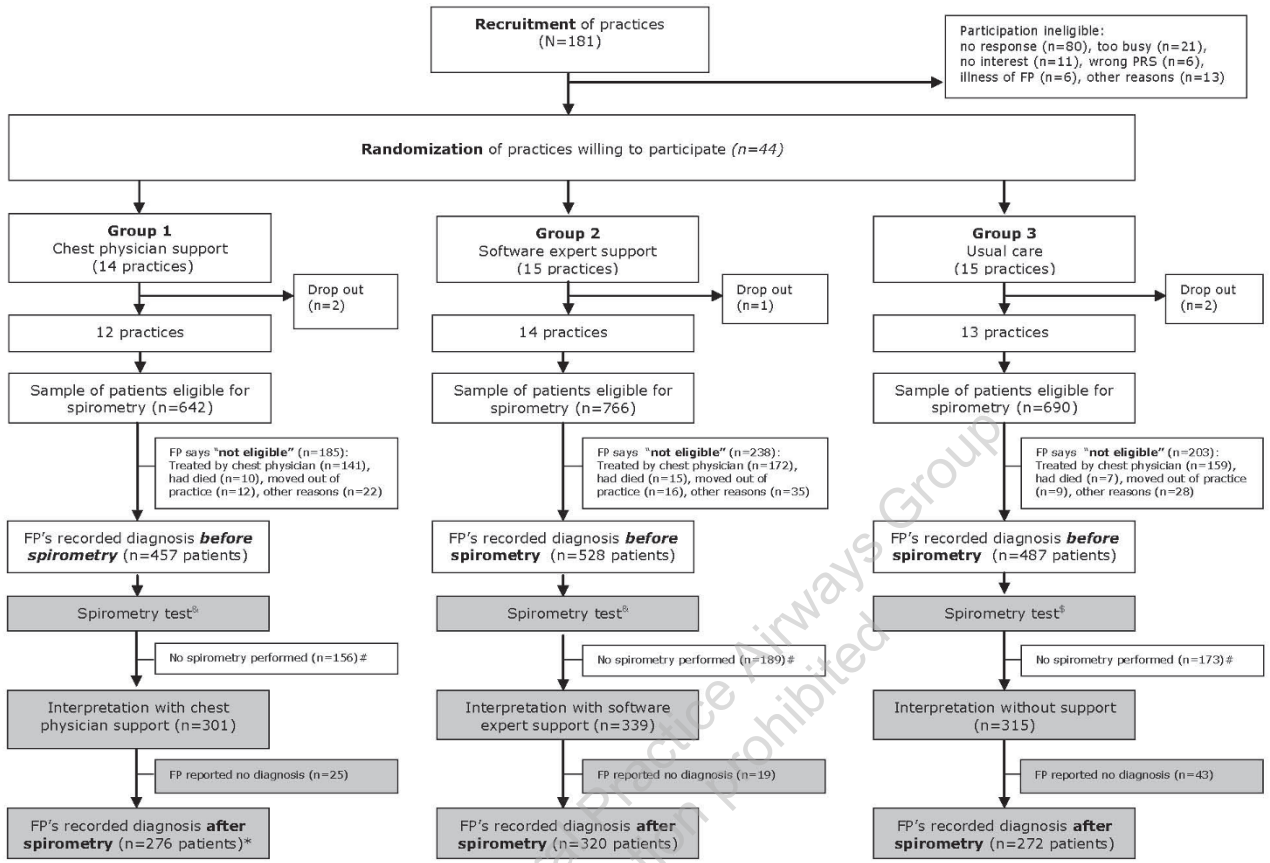
Participants

101 Practices responded to the mail (56%). Between February 2004 and May 2006 44 practices participated in the study (see Figure 1).

Five practices dropped out after randomisation. Dropout practices tended to have more experience with spirometry, a smaller practice population size, and less frequently employed a practice nurse (data not reported).

The weighted random practice population sample comprised 2098 patients. There was no difference between the three groups with respect to the proportion of patients who had had a spirometry test (54.6% chest physician support, 61.7% software expert support and 56.8% usual care) before this study (p=0.21). FPs recorded their diagnosis and planned management before spirometry in 1472

Figure 1. Participants to the present study.



Abbreviations: FP: family physician, PRS: patient record system

& Databases of the spirometry software were missing due to technical problems with PCs. Electronic data available for 174 (group 1), 239 (group 2) and 170 (group 3) patients.
# Reasons were if patients did not respond attend the spirometry test (29%); suffered from co morbidity (12%), had died (3%), had left the practice (9%), had undergone spirometry test recently (3%), felt they had no respiratory problems (5%), and other reasons (39%)
* no consultation used for 46 patients

patients. Spirometry was not performed in 517 (35%) of these patients. FPs reported no diagnosis after interpretation in 87 patients [chest physician group (n=25), software expert support group (n=19), usual care group (n=43)] because: the standard assessment form was lost (chest physician group 16%, software expert support group 26.3%, usual care group 39.5%); patients had left the practice (16%, 15.8%, 9.3%); patients had died (8%, 5.3%, 4.7%); patients were meanwhile under treatment from a chest physician (16%, 0%, 7%); FPs could not interpret the spirometry results (12%, 0%, 18.6%); and for other reasons (32%, 19%, 43%). FPs recorded their diagnoses and planned management again after spirometry in 868 patients. The analysis of all outcomes was based on 868 patients from 39 practices.

Baseline characteristics

85% of all staff (e.g. FPs, practice nurses, and practice assistants) attended the baseline spirometry workshop. The mean age of the sampled patients was 56.5 years (SD 14.3) (Table 1). There was no statistical difference between the three groups for the percentage predicted FEV_1 or FEV_1/FVC values.

Before spirometry, FPs recorded a total of 954 diagnoses (1.10 diagnosis per patient) (see Table 2). In 91% of patients the FPs recorded one diagnosis, and in the remaining 9% more than one diagnosis. The FPs in the software supported group less frequently reported more than one diagnosis (5.3%) compared to the FPs in the usual care group (12.5%) and chest physician support group (10.9%) (p=0.006). After spirometry, FPs recorded a total of 985 diagnoses (1.13 diagnoses per patient). In 87% of the patients FPs recorded one diagnosis, in the remaining 13% two or more diagnoses.

Primary outcome

Diagnoses changed after intervention in all groups: 47.8% (95% CI 41.8 to 53.9) for chest physician support; 45.0% (95% CI 39.5 to 50.6) for software support; and 53.3% (95% CI 47.2 to 59.4) for usual care (Table 3). Differences in

Table 1. Baseline characteristics of all 44 randomised general practices and 868 patients.

	Chest physician support	Software support	Usual Care
General practices			
Number of practices	14	15	15
Type of practice, n (%)			
- single handed	5 (36)	10 (67)	5 (33)
- duo	4 (29)	5 (33)	5 (33)
- group (≥ 3 FPs)	4 (29)	-	4 (27)
- multidisciplinary health care centre	1 (6)	-	1 (7)
Number of patients per FP, range (median)	783-2880 (1545)	712-3400 (1600)	640-2800 (1750)
Practice nurse present, % yes	29	47	33
Average experience (years) with spirometry of all FPs in practice, range (median)	0-11 (4.5)	0-14 (3.0)	1-10 (4.0)
Patients			
Number of patients	276	320	272
Age, mean (SD)	55 (14.4)	59 (14.3)	55 (13.9)
Gender, % female	54.7	58.1	62.5
Patients selected from practices' lists			
- with respiratory disease, n (%)	189 (69)	178 (56)	164 (60)
- with apparent respiratory disease, n (%)	87 (31)	142 (44)	108 (40)
Spirometry results			
Number of patients	174	239	170
FEV_1, mean (SD)	2.66 (0.84)	2.34 (0.90)	2.57 (0.89)
FEV_1 % predicted	87.80 (18.69)	83.12 (22.59)	88.26 (21.09)
FEV_1/FVC %, mean (SD)	75.73 (9.45)	72.02 (12.18)	71.71 (10.89)

Table 2. FPs' diagnoses in 868 patients.

FPs diagnoses (n=)	Before spirometry (n=954)	After spirometry (n=985)
Asthma	450	416
COPD	270	266
No respiratory disease	102	152
Asthma with persistent obstruction	52	66
Other diagnosis	80	85

proportions of changed diagnosis were not statistically significant: chest physician support versus usual care OR 0.79 (95%CI 0.49 to 1.30); software support versus usual care OR 0.72 (95% CI 0.45 - 1.15). The intra-cluster correlation was 0.065.

Secondary outcomes

There were no significant differences between chest physician support or software support compared with usual care for secondary outcomes (Table 3). Data on prescriptions were only available for 65% of the practices; the missing patients were more frequently female and slightly younger (data not reported).

FPs' self-scored perception of the influence of expert support for the interpretation of the spirometry test on assigning a diagnosis was [mean (SD)] 2.4 (1.2) with software support and 2.2 (1.7) with chest physician support; the latter low figure may have been affected by the fact that a chest physician was never consulted in 16% of cases.

Figure 2 depicts the direction of change of diagnosis from before to after spirometry. Generally, most changes were observed among FPs who did not receive expert support.

A prior diagnosis of COPD (Figure 2a) changed in ~35% into another diagnosis (mostly asthma). This shift in diagnosis was not statistically significantly different between the groups: chest physician support versus usual care OR 0.68 (95% CI 0.35 to 1.34); software support versus usual care OR 0.88 (95% CI 0.48 to 1.61).

Table 3. Impact of the spirometry interventions on outcomes.*

Indicators	Chest physician support (n=276)	p	Software support (n=320)	p	Usual Care (n=272)
Primary outcome					
Change of diagnosis,					
% (95%CI)	47.8 (41.8 - 53.9)	0.36	45.0 (39.5 - 50.6)	0.16	53.3 (47.2 - 59.4)
OR (95%CI)	0.79 (0.49 - 1.30)		0.72 (0.45 - 1.15)		1.0
Secondary outcomes					
Referral rate**,					
%	7.6	0.23	5.7	0.82	5.2
OR (95%CI)	1.53 (0.76 – 3.08)		1.09 (0.53 – 2.36)		1.0
Additional diagnostic tests#,					
%	8.7	0.32	18.1	0.21	12.5
OR (95%CI)	0.65 (0.28 – 1.51)		1.61 (0.76 – 3.41)		1.0
Medication changes $,					
% yes	32.7	0.25	38.9	0.97	39.0
OR (95%CI)	0.76 (0.47 – 1.21)		0.99 (0.65 – 1.52)		1.0

* P values apply to testing chest physician support versus usual care and software support versus usual care
Multilevel logistic regression analyses were performed for dichotomous variables .OR = Odds ratio, 95%CI = 95% Confidence Interval.
** Referrals included: chest physician, cardiologist, internist and ENT-surgeon.
# Additional diagnostic tests included: peak flow measurement, allergy test, diagnostic prednisolone test, chest X-ray, histamine provocation test and electrocardiography.
$ We report about 146 patients (usual care), 247 patients (software support), and 168 patients (chest physician support). Due to technical problems with software data for medication prescriptions were missing for 46.3% of the patients in usual care group, for 22.8% in software support group, and 39% in chest physician support group.

A prior diagnosis of asthma (Figure 2b) changed in ~30% of cases. This shift was not significantly different between groups: chest physician support versus usual care OR 0.65 (95% CI 0.32 to 1.31); software support versus usual care OR 0.55 (95% CI 0.27 to 1.12).

Finally, the diagnosis "no respiratory disease" (Figure 2c) changed in ~50% of cases (mostly into asthma or COPD). This shift in diagnosis was not significantly different between the groups; chest physician support versus usual care OR 0.61 (95% CI 0.22 to 1.72); software support versus usual care OR 0.85 (95% CI 0.34 to 2.13).

Subgroup analyses

There was a difference in change of diagnosis after intervention: changes were more frequent in patients with apparent respiratory disease (56.4%) than in patients with respiratory disease (43.6%) (p<0.001). In patients with respiratory disease this change was not significantly different between the groups: chest physician support versus usual care OR 0.85 (95% CI 0.49 to 1.47); software support versus usual care OR 0.83 (95% CI 0.48 to 1.43). In patients with apparent respiratory disease this change was also not significantly different between the groups: chest physician support versus usual care OR 0.76 (95% CI 0.37 to 1.55); software support versus usual care OR 0.52 (95% CI 0.27 to 1.01).

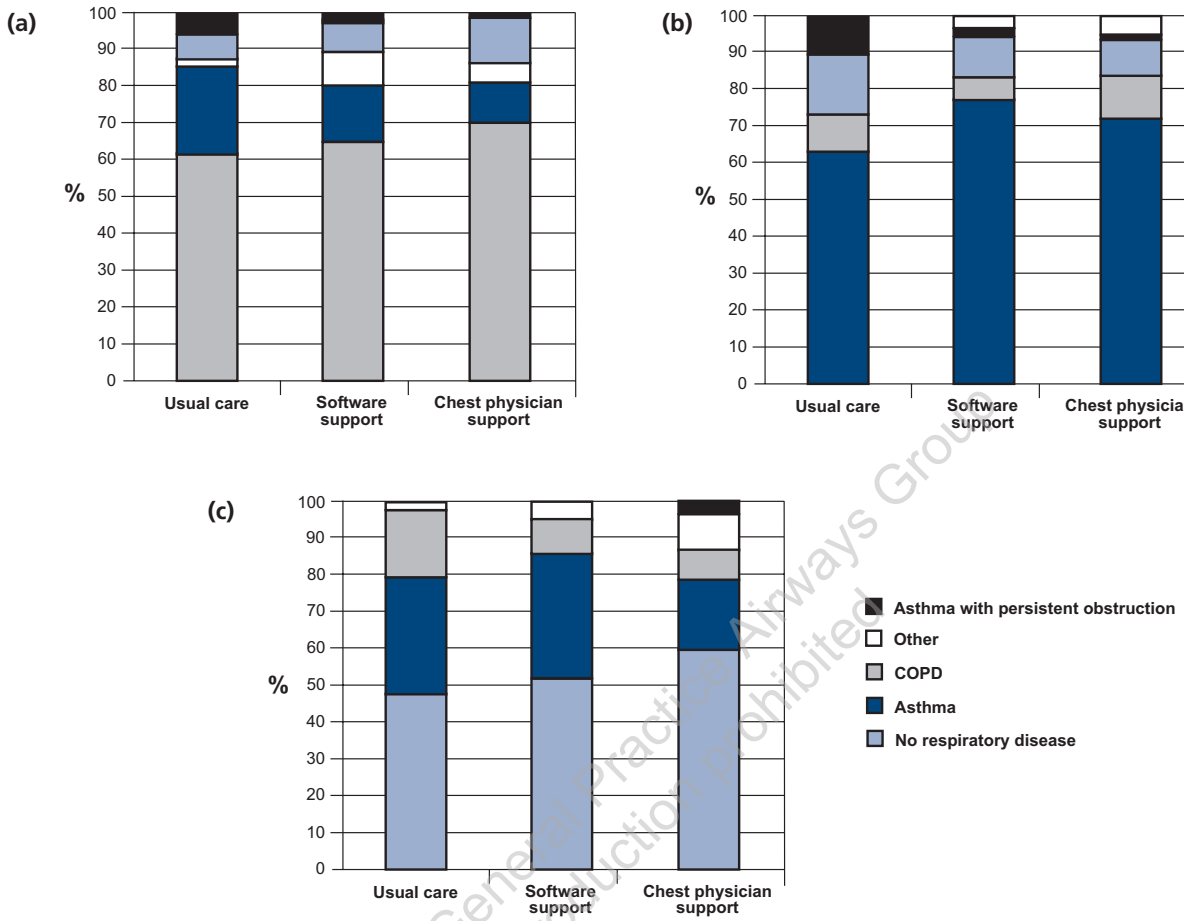
Discussion

Spirometry was important for FPs' diagnosis, but we found no added value – on FPs' decision-making in establishing a final diagnosis in patients with chronic respiratory symptoms – in adding chest physician support or software expert support. In over 40% of cases spirometry led to a modification of the diagnosis. Not surprisingly, diagnoses changed more often in patients in whom a formal diagnosis had not been made prior to spirometry, but this was the case in all three study groups. Overall, spirometry expert support did not seem to influence FPs' decision-making processes.

Strengths of the study

This is the first study that has addressed in a randomised trial the effect of chest physician support on FPs' diagnosis and management. We offered standardised training and supplied all practices with the same equipment, thus creating a uniform point of departure in the three study groups. To avoid investigator bias, analyses were performed blinded by both the investigators and the statistician (RA). As the participating family practices were not specifically selected the external validity of the results is good: despite the fact that the study was organised in the Eastern part of the country, we have no reasons to assume that the results are not applicable to other parts of the country where FPs perform spirometry in their own practice. We selected patients with respiratory disease

Figure 2. Diagnosis after spirometry in patients with a diagnosis before spirometry of COPD (a), asthma (b), and no respiratory disease (c).



for revision of their current diagnosis, and patients with apparent respiratory disease based on respiratory medication use for assessing a new diagnosis. For both categories of patients spirometry seems to have additional value.

Possible limitations

Our study has some limitations. We could only look at changes in FPs' diagnoses, rather than changes in the accuracy of their diagnoses. Although the latter option would have been more informative, there were perceived financial, practical and ethical barriers in sending all study patients to a medical specialist (i.e. a chest physician) in order to confirm and/or re-diagnose the patient in a short time. From our in-depth evaluation of software expert support we know that FPs' diagnostic accuracy was about 67%.[13]

Although we anticipated that support from a chest physician would have influenced FPs more often than the software support, FPs' perception of this kind of support on their diagnostic choices or decision-making was similar. One reason for this finding may be the fact that FPs in the chest physician group used restricted formats for the distance consultation, which included only spirometry results and medication. We reasoned that this kind of consultation limited to the spirometry test result would be more equal to the output from the software expert system with respect to the interpretation of the results. FPs in the chest physician group were not encouraged to report detailed medical history, symptoms or co-morbidity, which is frequently helpful in reaching a conclusion. By using this methodology the effect of the chest physician support has probably (but deliberately) been reduced beforehand.

Despite randomisation, we found some between-group differences in patient characteristics that might have influenced the results of this study. In the software support group the absolute and relative number of patients that had been evaluated was larger than in the other groups. Moreover, the mean FEV_1 and FEV_1% predicted values were lower. However, in the chest physician-supported group the mean FEV_1/FVC ratio was higher and the standard deviation smaller; thus this patient population was more homogeneous with less severe pulmonary obstruction.

Finally, we did not ask FPs if our method of patient selection matched their opinion of clinical relevancy. Therefore we cannot explain why many patients with apparent respiratory disease were being assigned a new diagnosis (Figure 2).

Relation with other studies

On the one hand the number of changed diagnoses was larger than we had anticipated in the sample size calculation. We assumed a 15% change in diagnoses in the usual care group after FPs' reassessment with the input of the new spirometry test, and a 30% change in each of the supported groups. Much to our surprise FPs' reassessment of diagnoses induced a change in about half of all diagnoses, regardless of the type of expert support. On the other hand the observed change of diagnosis after spirometry and the effects on pharmacotherapeutic management are in line with other studies;[18,19] however, these studies reported on a change of diagnosis (20-70%) after adding information (spirometry) required to demonstrate obstruction which was, for whatever reason, not available before. We introduced a next step: expert support.

Difficulties in differentiating between COPD and asthma appear to be common in primary care.[20] Changing a diagnosis does have consequences for clinical practice: a new diagnosis of asthma was commonly made in patients with a former diagnosis of COPD or apparent respiratory disease. In these cases prescriptions for respiratory medication (i.e. starting inhaled corticosteroid treatment) will need to be initiated. Another 'side-effect' of the study procedures – with possible clinical consequences – may have been that some patients with a clear history of asthma but with normal spirometry were deleted from the practice asthma register inappropriately in the chest physician group.

From a recent in-depth evaluation of software expert support we know that expert support does not seem to influence FPs' decision-making and that FPs' diagnostic accuracy was about 67%.[13] Another descriptive study found that an FP is able to predict a diagnosis of COPD or asthma correctly in up to 75% of cases based on simple criteria.[21] Both studies suggest that the added value of expert support on diagnostic accuracy is low. Recently, a systematic review showed that the effects of computerised support on doctors' performance in diagnostic evaluations were low.[22] For respiratory conditions, the study of Kuilboer *et al*. reported a positive effect of a guideline-based critiquing system on FPs' monitoring (not diagnosing) of asthma and COPD.[23] Contrary to a critiquing system that provides explanations based on an FP's formulated decision, the spirometry expert system we used in our study does not provide feedback to an FP's formulated decision; it automatically generates comments based exclusively on spirometric data. Theoretically, the correspondence model with the chest physician that we used resembles a critiquing system: FPs had to formulate their working diagnosis and treatment in order to get feedback on their facsimile from a chest physician. This kind of remote reporting is feasible[24] and there is a good concordance between paper consultations ("facsimile") and live consultations by chest physicians.[25] However, we did not find a statistically relevant influence on FPs' decision-making in this first randomised study on this topic.

Unanswered questions and future research

There is a dilemma. On the one hand FPs express a need for expert support[12] since interpreting spirometry seems difficult;[8,9] on the other hand trained FPs have been shown to diagnose respiratory conditions accurately.[13,26] Therefore, we should look for other FP-related factors that increase FPs' uncertainty in interpreting the tests. Qualitative studies are necessary to address this point.[27]

Although in research settings trained FPs have demonstrated that they can perform spirometry of sufficient quality,[14] the optimal model for performing high quality spirometry among less experienced FPs is unclear.[28] The current models with chest physician or software support do not seem to contribute to improving patient care. However, several COPD support services, in which chest physicians work together with trained respiratory nurses and a regional primary care laboratory, may be more appropriate in primary care.[19,29,30] Whether these services are superior (in terms of diagnostic accuracy) as compared to within-practice testing requires further research.

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Conflict of Interest declaration

Dr. Thoonen has received grants from AstraZeneca, Boehringer Ingelheim, Pfizer and GSK for educational purposes, congress travels and advising functions. Dr. Jacobs has received grants from Pfizer, AstraZeneca, GSK, and the Dutch Asthma Foundation to perform scientific research. Prof. Quanjer has received university grant monies, royalties from Micro Medical for expert software, and is a consultant (quality control) for a Novartis intervention study. None of these affiliations have any

bearing on the science, design of the study, nor its interpretation, best illustrated by the fact that the expert system did not come out favourably. Prof. Van Weel has received grant monies from MRC (ZonMW) and unrestricted research grants from various pharmaceutical companies.

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