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Feasibility and validation of telespirometry in general practice: The Italian ''Alliance'' study☆

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Summary
Introduction: At variance from office spirometry, telespirometry has not been tested as a tool for improving the ability of general practitioners (GPs) to manage chronic airway diseases.
Methods: After adequate training, 937 Italian GPs agreed to perform telespirometry in subjects attending their clinics who had risk factors, persistent respiratory symptoms, or a previous diagnosis of asthma or COPD. Each subject performed at least three forced expiratory manoeuvres using a turbine spirometer. Traces were sent by telephone to a Telespirometry Central Office, where they were interpreted by a pulmonary specialist, according to defined criteria. The result was sent in real time to the GP to assist the management of the patient.
Results: During 2 years, 20,757 telespirometries were performed, with a mean of 22.2 ± 25.2 examinations for each GP. 70% of the tests met the criteria for good or partial co-operation, allowing spirometric abnormalities to be detected in more than 40% of the tracings. The rate of telespirometries that could not be evaluated at all was reasonably low (9.2%). For a subset of the telespirometries, a comparison between acceptability criteria for telespirometry and those recommended for laboratory (ATS) or office spirometry showed that the majority of

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telespirometries with good co-operation satisfied completely, or with minor deviations, the ATS and Office criteria.
Conclusions: Telespirometry was well accepted by Italian GPs, who obtained acceptable screening traces in a large percentage of subjects. Therefore it might be considered a useful alternative to office spirometry in improving the management of chronic airway diseases by GPs.

Introduction

Asthma and chronic obstructive pulmonary disease (COPD) affect up to 10% of the general population.[1,2] COPD, in particular, is becoming ever more frequent, due to the increasing age of the population and the persistence of the main risk factors.[3] These diseases are responsible for a heavy socio-economic burden due to the direct and to indirect costs including loss of productivity.[4,5]

Early diagnosis and correct management are essential in order to reduce the burden of these diseases. In asthmatic subjects, early diagnosis and prompt initiation of inhaled corticosteroid treatment were associated with a better long-term prognosis.[6] A pre-clinical demonstration of persistent airway obstruction can help to recognize COPD early and can increase the possibility of halting the progressive decline in pulmonary function by smoking cessation.[7] Appropriate management of these diseases requires measurement of pulmonary function, which is strongly related to the level of asthma control[8] or to the prognosis of COPD,[9] as recommended by international guidelines.[10,11] Unfortunately, many patients with asthma or COPD have never undergone spirometry prior to the first evaluation by a pulmonary specialist, either as outpatients or as inpatients at the time of a hospital admission for an acute exacerbation.[12] The reasons for the underuse of spirometry, *at least in some countries like Italy*, are related not only to the poor recognition of asthma and COPD in the general practice, but also to inadequate implementation of guidelines, and to some technical factors such as poor access to pulmonary function laboratories, and the feeling that spirometry is complex and difficult to perform.[13] One study reported that whereas pulmonary specialists use spirometry to assess asthmatic patients, less than 50% of GPs in the USA do so.[14]

Several attempts have been made to improve the use of spirometry in general practice. Office spirometry has been standardised and proposed as a screening method for the early identification of subjects with asthma or COPD.[15] In some countries, widespread use of office spirometry detected a high prevalence of airway obstruction in subjects at risk with no or minimal symptoms.[16–18] In Italy, one study tried to assess whether office spirometry was able to improve the management of asthma and COPD, with inconsistent results.[19] Telespirometry (i.e., spirometry with simple equipment in a GP's clinic then sending the results by telephone to a central office where the data are processed, analysed and interpreted, and referring the results back to the GPs) has been used to monitor selected asthmatic patients living a long distance from the hospital, or COPD patients with some limitation to access to a hospital.[20,21] Until now no data have been reported on the use of telespirometry in GP's clinics for the screening of asthma and COPD.

This paper reports the results of an Italian study on the feasibility of telespirometry in general practice. The study, named ''Alliance'' to denote the link between pulmonary specialists and GPs in the management of airway obstructive diseases, involved a large number of GPs under the supervision of selected pulmonary specialists. This initiative aimed at improving the familiarity of GPs with spirometry, and telespirometry was chosen as a tool whereby GPs had some interaction with the pulmonary specialist located in the central laboratory in which the telespirometric data were analysed.

Subjects and methods

Study protocol

This was an observational study, involving a large sample of GPs from all regions of Italy. Fifty-one pulmonary units distributed throughout the country were asked to participate in the study. In each centre, a pulmonary specialist was selected to provide the education to a group of 20 GPs selected according to their willingness to perform telespirometry.

A Steering Committee defined the study design and identified the 51 pneumology units. Educational material on asthma, COPD and spirometry was prepared for the first teaching session. In each pulmonary unit, a 6-h educational session was performed with the 20 selected GPs: the topics were the diagnosis of asthma and COPD, the technique for performing spirometry and telespirometry, and the presentation of the study design.

The GPs could perform telespirometry in her/his general practice, in any subjects. Furthermore each GP was asked to select, from the general practice, subjects with known or suspected chronic airway disease, and to record their data on a case report form. The detailed selection criteria and the results of this part of the study are reported in a previous publication.[22] Each GP was equipped with a simple, portable pneumotachograph (Spirotel, MIR, Roma, Italy) to measure the main indices derived from a maximal forced expiratory manoeuvre, and to transmit these data by telephone to a Telemedicine Central Office, TCO (ITMS Telemedicina Italia, Genoa, Italy). After obtaining by the patient an informed consent, GPs performed simple spirometry (at least three blows in the Spirotel). *After that*, GP sent by telephone all tracings to the TCO. In real time, it was connected by telephone to the operator of the TCO who commented on the quality of *all* spirometric traces, and offered an interpretation of the results of the single patient. Then, the report was sent by

Table 1 Criteria for acceptability of the telespirometry.

Good co-operation	Two manoeuvres acceptable and reproducible
Partial co-operation	One or more acceptable manoeuvres, without reproducibility
No co-operation, only FEV_1 evaluable	No acceptable manoeuvres for FVC and no reproducibility, only FEV_1 evaluable
No co-operation at all	No acceptable manoeuvres for FEV_1 or FVC and no reproducibility

fax to the GP's office. All procedure required no more than 10 min. Bronchodilator test was not recommended, in order to make the procedure as simple as possible and not time-consuming.

The criteria used to assess the acceptability of a single expiratory manoeuvre were: time to peak flow $<$150 ms, back extrapolation $<$5% FVC (or 150 ml), lack of cough during expiration, expiratory time $\geq$3 s, and end-expiratory flow $<$0.2 l/s. The criteria used to accept single telespirometric tests are reported in Table 1. Reproducibility was defined as a difference in FEV_1 and in FVC between two manoeuvres of less than 5% and less than 200 ml. Acceptability criteria were scored from full co-operation to insufficient co-operation.

The result of the test was described according to the criteria reported in Table 2.

According to the interpretation of the telespirometry, GPs were asked to make a possible diagnosis for the individual patient observed (controlled or uncontrolled asthma or COPD), and to report on the case report form the type of intervention made as a consequence of the diagnosis (possible changes in the usual management, or beginning a new pharmacological treatment). The results of this part of the study are reported in a different manuscript submitted for publication.[22]

The local pulmonary specialist provided periodic educational sessions during and at the end of the study, in order to reinforce the interest in the study and to improve the performance of telespirometry.

Telespirometry

Spirotel is a small turbine spirometer which collects data from the expiratory manoeuvre and enables the measurement of FEV_1, FVC and PEF. A preliminary evaluation of the technical properties of the Spirotel was made by comparing the results obtained with this instrument in a sample of patients with asthma or COPD with those of spirometry performed in laboratory with a conventional spirometer (Biomedin, Padova, Italy). The concordance between the results of the Spirotel and the laboratory spirometer for FEV_1, FVC and PEF was excellent (data not shown).

Quality evaluation of telespirometry

Two of the authors (GA and PLP) conducted careful examination of all the spirometric traces performed up to June 2003 by the GPs of two centres (N = 296 telespirometries defined as good or partial co-operation). The results of each telespirometry test were analysed according to the criteria used for quality evaluation of laboratory spirometry (ATS recommendation)[23] and of office spirometry.[15] The percentage of the telespirometries which satisfied the acceptability criteria of ATS or office spirometry was computed.

Statistical analysis

A descriptive analysis was performed, reporting data with continuous distributions as number of observations, means and standard deviations, and categorical data as absolute and percent frequencies.

Results

Fifty-one pulmonary centres recruited 1076 GPs; 937 of these performed at least one telespirometry test. The study started in October 2002, and ended in October 2004. During this period, the 937 GPs sent data from 20,757

Table 2 Interpretation of the results of the telespirometry.

Normal telespirometry	$FEV_1/FVC \geq 70\%$, and $FEV_1 \geq 80\%$ of predicted
Mild airway obstruction	$FEV_1/FVC < 70\%$ and $FEV_1 \geq 80\%$ of predicted
Moderate airway obstruction	$FEV_1/FVC < 70\%$ and FEV_1 between 79 and 50% of predicted
Severe airway obstruction	$FEV_1/FVC < 70\%$ and FEV_1 between 49 and 30% of predicted
Very severe airway obstruction	$FEV_1/FVC < 70\%$ and $FEV_1 < 30\%$ of predicted
Abnormal telespirometry, but not clear airway obstruction	$FEV_1/FVC \geq 70\%$ and $FEV_1 < 80\%$ of predicted
Suspected airway obstruction	$FEV_1/FVC \geq 70\%$ and $FEV_1 \geq 80\%$ of predicted but with abnormal flow-volume loop morphology
Only FEV_1: normal	$FEV_1 \geq 80\%$ of predicted
Only FEV_1: abnormal	$FEV_1 < 80\%$ of predicted

telespirometric tests to the TCO, with a mean of 22.2 ± 25.2 tests per GP (range: 1–451). The tests were related to 17,910 subjects (10,597 males and 7313 females), with a mean age of 50.3 ± 17.6 years. The time course of the recruitment of the patients is reported in Fig. 1. The majority of patients were recruited in the first 14 months of the study. In the first year of the study, 70% percent of GPs performed more than 10 telespirometric tests, and 50% of them more than 20 tests.

The results of all the telespirometric tests are reported in Table 3. Traces from only 9.2% of the telespirometric tests were considered not evaluable at all (when no single acceptable FEV_1 was measurable). More than 20% of the tests allowed only the measurement of FEV_1 (in these cases, FVC was not measurable, mainly because the duration of expiration was shorter than 3 s). Thus, the criteria defining good and partial co-operation were fulfilled by 70% of the telespirometric tests.

Evidence of mild to severe airway obstruction was observed in 19.2% of all the telespirometric tests, but in 27.4% of those tests with a good or acceptable co-operation. A small number of the tests were suggestive of airway obstruction according to the shape of the flow-volume curve (3.3% of all tests), while another consistent percentage (8.5% of all tests) of the telespirometric tracings showed some abnormalities (mainly a concomitant reduction in FEV_1 and FVC with normal FEV_1/FVC ratio) not clearly attributable to airway obstruction. Some abnormality was found in 39.2% of all evaluable telespirometric tests, and in 44.3% of those tests that fulfilled the acceptability criteria of good and partial co-operation.

A sample of 296 telespirometric tests which satisfied the criteria of good and partial co-operation were analysed in comparison to the ATS and Office quality criteria (Tables 4 and 5). Among the 296 tests, 34.5% completely satisfied all ATS criteria for acceptability of the test (at least three acceptable manoeuvres, expiratory duration >6 s, reproducibility of FEV_1 and FVC). In another 48.7% ATS criteria were satisfied except for one criterion (sometimes two and not three acceptable manoeuvres, sometimes a short expiratory duration in one or more manoeuvres, sometimes a lack of reproducibility of FVC measurements); in this group were included telespirometries which do not satisfy ATS acceptability criteria only for the expiration time <6 s (24.3% of the full sample). The percentage of telespirometric tests that did not satisfy more than one of ATS criteria was low (16.9%). When considering acceptability according to Office criteria, it was found that 62.5% of all the telespirometric tests considered acceptable for good co-operation also satisfied the main criteria (A + B+ C) of office spirometry.

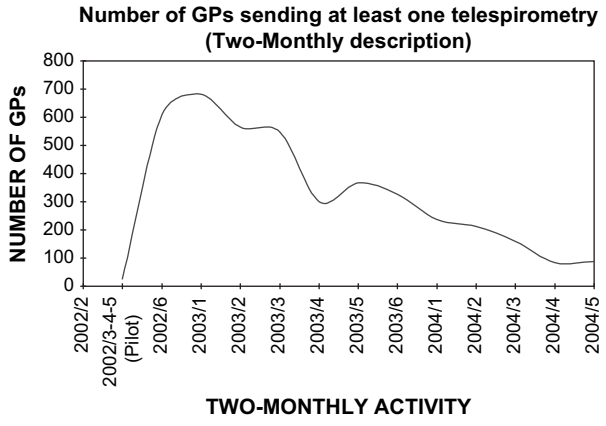

Figure 1 Number of GPs sending at least one telespirometry (two-monthly description).

Table 3 Results of the telespirometries, according to the criteria of acceptability and interpretation reported in Tables 1 and 2.

	N	%
Good and partial co-operation		
Normal telespirometry	8081	38.9
Mild airway obstruction	925	4.5
Moderate airway obstruction	1968	9.5
Severe airway obstruction	936	4.5
Very severe airway obstruction	154	0.7
Abnormal spirometry, but not clear airway obstruction	1754	8.5
Suspected airway obstruction	694	3.3
Only FEV_1 evaluable		
Normal FEV_1	3370	16.2
Abnormal FEV_1	962	4.6
Not evaluable	1913	9.2
Total telespirometries	20,757	100.0

Discussion

The results of this study show that Italian GPs accept telespirometry as an *exploratory* useful way of improving the assessment of patients with suspected obstructive pulmonary diseases, and that they are able to perform acceptable

Table 4 Acceptability, according to ATS criteria, of the telespirometries that satisfied the criteria of good and partial co-operation (see Table 1).

	No.	%
Good and partial co-operation (telespirometry criteria)	296	100
All ATS criteria satisfied	102	34.5
Only two acceptable manoeuvres satisfying the ATS criteria	57	19.2
All ATS criteria satisfied, except expiratory time <6 s in one or more manoeuvres	72	24.3
All ATS criteria satisfied, except FVC reproducibility	15	5.1
Two or more ATS criteria not satisfied	50	16.9

Table 5 Acceptability, according to Office criteria, of the telespirometries that satisfied the criteria of good and partial co-operation (see Table 1).

	No.	%
Good and partial co-operation (telespirometry criteria)	296	100
Office A (two acceptable manoeuvres, and FEV_1/FVC reproducibility lower than 100 ml)	115	38.9
Office B (two acceptable manoeuvres, and FEV_1 reproducibility between 101 and 150 ml)	59	19.9
Office C (two acceptable manoeuvres, and FEV_1 reproducibility between 151 and 200 ml)	11	3.7
Office D (only one acceptable manoeuvre, or more than one with FEV_1 reproducibility greater than 200 ml)	0	0
Office F (no acceptable manoeuvres)	111	37.5

''screening'' spirometric tracings in a high percentage of subjects.

The mean number of telespirometries sent by each GP was more than 20 during the period of the study. Considering the high variability of acceptance by GPs, more than one third of GPs used telespirometry frequently during the first year of the study (more than 20 tests). To our knowledge, this is the first experience of the use of telespirometry in such a large group of GPs. Up to now telespirometry has been employed only in very particular situations.[20,21] In comparison with other experiences with office spirometry,[19] in this study telespirometry was accepted *by a large part of the GPs* because they were able to communicate and interact with the pulmonary specialist in the TCO just a few minutes after performing the test. This interaction improved the familiarity with the performance and the interpretation of the test, leading to an appreciation that the test was reliable and useful for the management of the single patient. This fact is particularly important in countries, such as Italy, where office spirometry is poorly used, unlike in the USA or in north European countries.[14,18] *Unfortunately, due to the lack of a persistent access to the TCO and the limitation in the time that Italian GPs may spend for this activity, the use of telespirometry was interrupted.*

The criteria used for the acceptability of telespirometry were different from those used for laboratory spirometry[23] or office spirometry.[15] This was due to the lack of full control by the GP during the performance of the telespirometry. The Spirotel does not display the flow–volume curve either during or after performance of the test, and only information about the characteristics of single traces (e.g. expiratory time or starting point) was immediately available to the GPs. However, the GPs did receive comments on the telespirometry just a few minutes after performing the test, and were often able to repeat the test immediately on the same patient, if needed. Taking into account these factors, associated with the exploratory aim of the study, the criteria used to evaluate the acceptability of the telespirometries differed from ATS and Office criteria. The main difference between our telespirometry and ATS/Office criteria was the expiration time: we chose 3 s instead of 6 s, as recommended for ATS/Office spirometry,[15,23] because we did not want to exclude a high percentage of telespirometries, and because the definition of FEV_6 as an important measure in office spirometry had not been widely accepted at the time the study was planned.[24] However, the 6 s criterium was not satisfied in 24.3% of the telespirometries defined as showing good or a partial co-operation. This could have reduced the sensitivity of the telespirometries to detect airway obstruction, without loss of specificity. At least two acceptable traces were obtained in a large proportion of subjects, while the lack of reproducibility for FVC was poorly represented. The concordance between telespirometry criteria and Office criteria was better, since more than 60% of the telespirometric tests defined as showing good co-operation also achieved level A–C of acceptability for Office spirometry. Therefore, the concordance between telespirometry and ATS or Office criteria was acceptable, and suggests that telespirometry can be a reasonable surrogate for screening spirometry.

The rate of telespirometric examinations that did not allow any reasonable information on pulmonary function was low, showing that in the majority of patients with suspected chronic airway diseases, telespirometry can provide GPs with additional informations for the management of their patients.

Among telespirometric examinations in which the level of co-operation was good, the rate of functional abnormalities was high (about 40% of all acceptable telespirometric tests). This is dependent on the criteria used by GPs to select patients for the telespirometry examinations, which included subjects at risk of asthma or COPD but also subjects with chronic respiratory symptoms or a previous diagnosis of asthma or COPD.[22] In addition to the classically defined mild to severe airway obstruction, we also included a category of mild abnormalities that are not diagnostic of airway obstruction but that could require further functional evaluation. This category included telespirometries with suspected airway obstruction (normal FEV_1 and FEV_1/FVC ratio, but a flow-volume loop morphology suggestive of initial airway obstruction) and accounted for 3.3% of all telespirometric traces. The presence of ''borderline'' categories of possible spirometric abnormalities might increase the sensitivity of the test, also considering the possibility of underevaluating airway obstruction due to the limitation in the end-phase of telespirometry. Among the abnormal telespirometric tests, we also included those with a concomitant reduction in FEV_1 and FVC but with a normal FEV_1/FVC ratio, which accounted for 8.5% of all the examinations. Recent

recommendations suggest that patients with a concomitant reduction in FEV_1 and FVC and normal FEV_1/FVC ratio should undergo a bronchodilator test.[25]

In conclusion, this study shows that telespirometry is well accepted and can be easily performed by a large number of GPs. A comparison with well-accepted criteria for quality, as recommended for laboratory spirometry and office spirometry, shows that telespirometry can reach acceptable levels of quality for screening spirometry. The rate of functional abnormalities detected in this large sample of subjects was appropriate for the selection criteria. Although neither office spirometry nor telespirometry can be considered a substitute for laboratory spirometry, telespirometry can be considered as a useful alternative to office spirometry in improving the management of patients with chronic airway diseases by GPs.

Conflict of interest

All authors declare that they have no conflict of interest to disclose. Paolo Ferri is an employer of AstraZeneca Italy which supported the study by an unrestricted grant.

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