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Spirometry in Primary Care in Navarre, Spain

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OBJECTIVE: To analyze the use and quality of spirometry in primary care settings in Navarre, Spain.

PATIENTS AND METHODS: A questionnaire was completed simultaneously by professionals responsible for spirometry in all of the primary health care centers in Navarre. Data were collected on availability, model of spirometer, frequency of use, calibration, methods, personnel responsible for testing, and training of personnel. Then, baseline spirometry without a bronchodilator test was performed in 171 patients in their primary health care center and then the test was repeated on the same day in a hospital pneumology department. Spirometry was supervised by 2 pneumologists who jointly assessed the acceptability of the flow-volume curves. The quality of spirometry was assessed according to the recommendations of the American Thoracic Society and the interpretation of spirometry results according to the criteria of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR).

RESULTS: A total of 90.9% of primary health care centers in Navarre have a spirometer, although 22% of those spirometers have never been used. Only 2 centers performed between 10 and 20 spirometry tests per week and none performed more than 20. In 96% of primary health care centers the spirometers were not regularly calibrated. The professionals who performed spirometry were not dedicated for that task in 51.2% of cases, and the mean period of supervised training was 10 hours. When comparisons were made between the mean values obtained in the primary care centers and the pneumology department, statistically significant differences were detected for forced vital capacity (*P*<.0001) and forced expiratory volume in the first second (*P*=.0002). Significant differences were also found between the flow-volume curves performed in the 2 different care settings for the initial and end portions of the curve as well as for the slope. The criteria for reproducibility recommended by the American Thoracic Society were not met in 76% of cases for forced vital capacity and 39.7% of cases for forced expiratory volume in the first second. Incorrect functional diagnosis occurred in 39.7% of spirometry tests and there was a tendency in the primary care settings to falsely diagnose patterns as restrictive and to inadequately classify the severity of obstruction.

CONCLUSIONS: Despite the fact that spirometers are available in the majority of primary health care centers in Navarre, we found a marked underuse of these devices and little compliance with recommendations for the use of spirometry. Furthermore, the quality of the measurements performed in this care setting was very low.

Key words: *Spirometry. Primary care. Use. Quality of health care.*

La espirometría en atención primaria en Navarra

OBJETIVO: Analizar la utilización y calidad de la espirometría por parte de atención primaria en Navarra.

PACIENTES Y MÉTODOS: Se realizó una encuesta simultánea a los profesionales responsables de las espirometrías de todos los centros de salud (CS) de Navarra recogiendo datos sobre la disponibilidad, modelo de espirómetro, frecuencia de realización, calibración, metodología, personal encargado de las pruebas y su preparación. Posteriormente a 171 pacientes, a los que se había realizado una espirometría basal sin prueba de broncodilatación en su CS, se les repitió la prueba el mismo día en el laboratorio de neumología; a la hora de la inclusión de los datos, 2 neumólogos supervisaron todas las espirometrías y valoraron conjuntamente la aceptabilidad de las curvas flujo-volumen. La calidad de las espirometrías se determinó siguiendo las recomendaciones de la American Thoracic Society y la interpretación de éstas según los criterios de la Sociedad Española de Neumología y Cirugía Torácica.

RESULTADOS: El 90,9% de los CS de nuestra comunidad disponía de espirómetros y el 22% de ellos no los utilizaba nunca. Sólo 2 CS realizaban entre 10 y 20 espirometrías a la semana y ninguno más de 20. El 96% de los centros de atención primaria no calibraba de forma reglada los aparatos y el 51,2% de los profesionales que realizaban las espirometrías no eran fijos, con 10 h de media de aprendizaje supervisado. Se detectaron diferencias estadísticamente significativas al comparar las medias de los valores de la capacidad vital forzada y del volumen espiratorio forzado en el primer segundo obtenidos en atención primaria y en la consulta de neumología (p < 0,0001 y p = 0,0002, respectivamente); también fueron significativas las diferencias encontradas en la realización de las curvas flujo-volumen entre los 2 niveles asistenciales, tanto en su inicio como en su pendiente o en su finalización. Se pudo comprobar, en un 76% de los casos para la capacidad vital forzada y en un 39,7% para el volumen espiratorio forzado en el primer segundo, un incumplimiento de los criterios de reproducibilidad recomendados por la American Thoracic Society. Se realizaron diagnósticos funcionales erróneos en el 39,7% de las espirometrías, con una tendencia a diagnosticar patrones falsamente "restrictivos" y a clasificar inadecuadamente la gravedad de la obstrucción en atención primaria.

CONCLUSIONES: Pese a que la mayoría de los CS de nuestra comunidad dispone de espirómetros, hemos observado una acusada infrautilización de éstos, un escaso seguimiento de las recomendaciones para la realización de la espirometría por parte de atención primaria y escasa calidad de la efectuada en este medio asistencial.

Palabras clave: *Espirometría. Atención primaria. Utilización. Calidad.*

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Introduction

Forced spirometry is essential for diagnosis, monitoring, and management of respiratory diseases and represents the main diagnostic tool for chronic obstructive pulmonary disease (COPD). Various national and international clinical guidelines and initiatives recommend increased use of the technique.[1-3] In Spain, outpatient screening programs for COPD have been developed for smokers.[4] Nevertheless, it is clear that this diagnostic test continues to be used very little in primary care settings.

The aim of this study was to analyze the availability of spirometers, the understanding of spirometric test procedures, and the use of spirometry in primary care, as well as to assess the quality of the spirometry performed in this care setting in the Autonomous Community of Navarre, Spain.

Patients and Methods

Study Design and Population

The study was divided into 2 parts. The aim of the first part was to determine the status of spirometry in primary care in Navarre in terms of knowledge, resources, and use. To this end, a questionnaire was completed simultaneously in all primary health care centers in the region, together serving a total of 585 000 inhabitants. In the second part, a prospective study was performed to assess the quality of spirometry performed in primary care settings.

Study Procedures and Selection Criteria

The directors of the various health care centers were informed of the study by the department responsible for primary care in Navarre and their collaboration requested. Data were collected by questionnaire (Appendix 1). Information was obtained from the individuals responsible for spirometry in the health care centers between October and November, 2004.

Centers that performed spirometry were divided into 2 groups depending on the number of tests that were performed per week (group 1, 5 or more spirometry tests per week; group 2, fewer than 5 tests per week). To undertake the second part of the study, it was first confirmed that there were no differences between the health care centers in the region of Pamplona and those in the rest of Navarre in terms of the model of spirometer and the time commitment and training of personnel responsible for performing spirometry. Then, 11 centers in Pamplona serving a population of 177 813 (representing 30.3% of the total population of Navarre) were selected at random: 4 from group 1 (serving a population of 90 643) and 7 from group 2 (serving a population of 87 170).

Over a period of 3.5 months (from January 17 to April 30, 2005) the doctors in each of the health centers were asked to obtain consent for participation in the study from those patients for whom spirometry was to be requested for any reason, so long as they met the criterion of not having undergone other tests in specialist care services.

Baseline spirometry without bronchodilator test was performed in each patient in their health center, following the procedures normally used in the center. Spirometry was performed by those members of the nursing staff who were usually responsible for the procedure and patients were instructed not to use bronchodilators until a second test had been performed. In the afternoon of the same day, spirometry was repeated with a bronchodilator test by nursing staff in a specialist pulmonology department according to the guidelines of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR),[5] using a Datospir 100® spirometer (Sibel, Barcelona, Spain), the model of spirometer available in most health care centers in Navarre. Prior to the second spirometry tests, the nurses collected a series of data using a specifically designed questionnaire (Appendix 2).

To ensure that the tests performed in the pulmonology department could be used as a reference, a double calibration of the spirometer was performed on a daily basis, one using a 3 L calibration syringe and another by performing spirometry with control individuals from the pneumology nursing staff. All spirometry, whether in the health care centers or the pneumology department, was supervised at the time of data collection by 2 experienced pneumologists who jointly assessed the acceptability of the flow-volume curve and classified the initial and end portions of the curve along with its slope into 2 groups (correctly or incorrectly performed). A maneuver was considered to be correctly performed if it presented a sharp onset with a smooth, uninterrupted curve and a terminal phase that was neither perpendicular nor sharp and with an overall expiration time of at least 6 seconds.

The quality of spirometry tests was assessed based on the recommendations of the American Thoracic Society (ATS).[6] Good reproducibility for measurements of forced vital capacity (FVC) and forced expiratory volume in the first second (FEV_1) was considered to be indicated when the differences between the best measurements in primary and specialist care settings were less than 200 mL and when those differences were less than 5% of the absolute value in specialist care, spirometry having been performed in each setting on the same day and using similar spirometers. Classification of spirometry data was performed based on SEPAR guidelines.[2]

Statistical Analysis

A unified database was generated and statistical analysis was performed using the statistical packages SPSS for Windows and G-Stat. The goodness of fit of the sample to a normal distribution was assessed using the Kolmogorov-Smirnov test. For the descriptive study, the quantitative data are expressed as means (SD) and qualitative data as percentages. The differences between the mean values for FVC and FEV_1 were analyzed using the Wilcoxon test and the Student *t* test for related samples. The similarity of the distributions was assessed with the nonparametric Kruskal-Wallis test; the shape of the curves was assessed by comparison of 2 proportions. In addition, the correlation between the measurements of FVC and FEV_1 in the different care settings was assessed using Pearson's correlation coefficient and the intraclass correlation coefficient. A *P* value of less than .05 was considered statistically significant in all analyses.

Results

The questionnaire was completed by all of the health care centers in Navarre. Of those, 50 (90.9%) had spirometers, although 11 (22%) never performed spirometry. Table 1 shows the results obtained in the first part of the study. In 83.7% of the health care centers in which the model of spirometer available was known, the device was a Datospir 100. Only 2 centers performed between 10 and 20 spirometry tests per week and none performed more than 20. In 96% of primary health care centers, routine calibration of equipment was not carried out, and when calibration was undertaken—with a periodicity that ranged from once a

TABLE 1
Spirometry Performed in Health Care Centers in Navarre, Spain*

Number of centers surveyed	55 (100%)
Rural	34 (61.8%)
Urban	21 (38.1%)
Spirometer available	55 (100%)
Yes	50 (90.9%)
No	5 (9.1%)
Model of spirometer	50 (100%)
Datospir 100®	36 (72%)
Datospir 120®	4 (8%)
Spirobank®	1 (2%)
Posh-Millans®	1 (2%)
Sony 1®, 2%	1 (2%)
Unknown	7 (14%)
Awareness of the type of reference values used with the equipment	50 (100%)
Yes	2 (4%)
No	48 (96%)
Number of spirometry tests performed per week	50 (100%)
None	11 (22%)
<5	31 (62%)
5-10	6 (12%)
10-20	2 (4%)
>20	0
Availability of a thermometer/barometer	50 (100%)
Yes	4 (8%)
No	46 (92%)
Availability of a calibration syringe	50 (100%)
Yes	7 (14%)
No	43 (86%)
Daily calibrations	50 (100%)
Yes	2 (4%)
No	48 (96%)
Instructions provided systematically prior to spirometry	39 (100%)
Yes	30 (76.9%)
No	9 (23%)
Prior explanation of spirometry to the patient	39 (100%)
Yes	38 (97.4%)
No	1 (2.5%)
Professional responsible for performing spirometry	39 (100%)
Registered nurse	37 (94.8%)
Doctor	2 (5.1%)
Dedicated professional	39 (100%)
Yes	19 (48.7%)
No	20 (51.2%)
Supervised training of staff responsible for spirometry	39 (100%)
Yes	25 (64.1%)
No	14 (35.9%)

*Data are shown as number (%).

month to once a year—the process was only performed and supervised by a technician. In 94.8% of health centers, nursing staff were responsible for performing spirometry and in 51.2% of cases the staff were not permanently assigned to that task; the rotation of this responsibility occurred daily in 55% of cases, weekly in 40%, and monthly in the remaining 5% of cases. In 64.1% of cases, the professionals responsible for spirometry reported having received some kind of supervised training in the use of the technique; the mean length of supervised training was 10 (11.57) hours—once data was eliminated for 2 nurses who had received particularly extensive training as a result of having worked for a number of years in pneumology in 1 case and allergology in the other.

TABLE 2
Patient Characteristics*

Total number of patients	171 (100%)
Age, mean (SD), y	51.75 (16.8)
Sex	
Male	87 (50.8%)
Female	84 (49.1%)
Education	163 (100%)
No schooling	13 (7.9%)
Primary level education	90 (55.2%)
Secondary level education	39 (23.9%)
University education	21 (12.8%)
Smoking habit	166 (100%)
Nonsmoker	51 (30.7%)
Active smoker, >40 pack-years	40 (24%)
Active smoker, <40 pack-years	26 (15.6%)
Ex-smoker of at least 6 months, >40 pack years	24 (14.4%)
Ex-smoker of at least 6 months, <40 pack years	25 (15%)
Reason for spirometry	168 (100%)
Suspected COPD	13 (7.7%)
Suspected asthma	13 (7.7%)
Dyspnea	42 (25%)
Other	100 (59.5%)

*Data are shown as number (%) unless otherwise indicated.
COPD indicates chronic obstructive pulmonary disease.

To assess the quality of spirometry performed in primary care, 203 patients were tested twice, once in this setting and again in a pneumology department. Thirty-two patients were excluded from the analysis: 15 for not having performed sufficiently reproducible maneuvers in the pneumology department and 17 for having used bronchodilators or for having undergone spirometry previously in specialist care settings. A total of 171 patients were included in the study (90 in group 1 and 81 in group 2).

A Datospir 100 spirometer was used with 131 patients in the health care centers. The mean age was 51.7 (16.8) years (range, 15-81). Other patient characteristics are shown in Table 2. The mean weight of patients in the health centers was 74.6 kg, the same as the mean recorded in the pneumology department. In contrast, differences were observed in the mean height, presumably due to inaccuracies or absences in the measurements (165.2 cm in the primary care centers and 163.7 cm in the pneumology department).

Table 3 shows the analysis of the spirometry test data. The differences between the mean values for FVC and FEV_1—analyzed using the Student *t* test for paired samples—were statistically significant in both cases ($P<.0001$ and $P=.0002$, respectively). The Kolmogorov-Smirnov test was used to confirm that the sample data was normally distributed and, given that a level of significance of 10% would be sufficient to reject that hypothesis on the basis of robustness, comparisons were made using the Wilcoxon test, the results of which were consistent with those obtained using the Student *t* test

($P<.001$ for FVC and $P<.001$ for FEV_1). The correlation between the 2 samples was also assessed using Pearson's correlation coefficient and the intraclass correlation coefficient ($r=0.85$ with both tests for FVC and $r=0.95$ with both tests for FEV_1). Table 3 also shows the number of spirometry measurements performed correctly and incorrectly for the 3 points analyzed (initial and terminal portions and slope). In this case, the differences were statistically significant; the differences were more pronounced at the onset of the maneuver, while the least marked differences were seen in the slope. Applying the reproducibility criteria recommended by the ATS, 130 patients (76%) presented differences of more than 200 mL for FVC and 68 (39.7%) for FEV_1; applying the stricter reproducibility criteria of differences of less than 5%, 139 patients (81.2%) did not meet those criteria for FVC and 102 (59.6%) for FEV_1.

When the differences between the values obtained were assessed for each health care center, it was found that 1 of them often showed higher values than those obtained in the pneumology department. To validate the data initially obtained in all the centers, the same tests were evaluated once that center was removed from consideration; the results were then found to be consistent.

When the records for groups 1 and 2 (more or less than 5 spirometry measurements per week) were compared to confirm whether frequent use of spirometry influenced the results, no statistically significant differences were observed ($P=.1042$ for FVC and $P=.4854$ for FEV_1).

Table 4 shows the extent of agreement between lung function diagnosis by spirometry in primary care and in the pneumology department. Incorrect diagnosis was seen in 68 cases (39.7%) and there was a tendency in the primary care settings to falsely diagnose patterns as restrictive and to inadequately classify the severity of obstruction.

TABLE 3
Analysis of Spirometry*

	Health Care Center	Pneumology Department	*P*
Assessment of flow-volume curve			
Initial phase, performed correctly	131 (76.6%)	156 (91.23%)	.0002
Slope, performed correctly	133 (77.8%)	151 (88.3%)	.0095
Terminal phase, performed correctly	145 (84.8%)	164 (95.91%)	.0005
Mean FVC, mL	3423.9	3794.6	<.0001
Mean FEV_1, mL	2542.3	2626.9	.0002

*Data are shown as number (%) unless otherwise indicated.
FVC indicates forced vital capacity; FEV_1, forced expiratory volume in the first second.

Discussion

The importance of spirometry in the diagnosis, follow-up, and prognosis of respiratory diseases such as asthma and COPD is unquestionable. The need for universal use of spirometry for the early diagnosis of respiratory diseases is now fully accepted in both primary and specialist care settings. Even the SEPAR consensus conference on COPD recommended that spirometry be used in primary care centers for all smokers aged over 40 years who suffered from cough, expectoration, or dyspnea, provided established guidelines for spirometry were followed and appropriately trained professionals were carrying out the test.[3] Nevertheless, in the few epidemiological studies that have been performed, marked underuse of this diagnostic test has consistently been found in primary care, and in many studies low quality has been reported for the tests performed in this care setting.[7-11]

The results of this study also show that spirometry is used very little in primary care in Navarre: in 29% of health care centers spirometry was never performed, in 56.3% it was performed fewer than 5 times per week (in some cases on very few occasions per year), and no health centers performed more than 20 spirometry tests per week. Although one of the reasons generally offered to explain the low utilization of spirometry in primary care has been the limited availability of equipment,[4,8-12] this cannot be applied in our case, since 90% of health centers in Navarre, serving more than 95% of the population, have access to spirometers. We observed that compliance with national and international recommendations on the use of spirometry was poor in primary care: calibration of spirometers was rarely performed and in more than half of all health care centers individuals responsible for performing spirometry were nurses who did not have an ongoing commitment to this task and who had received limited supervised training. These conditions explain the poor quality of test results and, in our opinion, represent one of the main explanations for the restricted use of this important diagnostic test in primary care in Navarre.

One important factor to take into consideration when

TABLE 4
Agreement Between Diagnosis of Pulmonary Function Obtained by Spirometry in Primary Care and in a Pneumology Department

Diagnoses Performed in a Pneumology Department	Diagnoses Performed in Primary Care						
	Normal	Mild Obstruction	Moderate Obstruction	Severe Obstruction	Mild Nonobstructive Deficit	Mixed	Total
Normal, n=69	54	5	0	0	10	0	69
Mild obstruction, n=71	20	26	6	1	16	2	71
Moderate obstruction, n=17	0	2	11	1	2	1	17
Severe obstruction, n=2	0	0	1	1	0	0	2
Mild nonobstructive deficit, n=12	1	0	0	0	11	0	12
Total	75	33	18	3	39	3	171

assessing our results is that in all cases the 2 spirometry tests were performed in each patient on the same day. In previous studies comparing the quality of this test in primary care, a varying number of days passed between the 2 tests (on occasions up to 30).[4,13,14] In our opinion, such a period of time between measurements could have a greater effect on the results than the fact that the first spirometry test was performed in the morning and the second performed in the afternoon.

The Pearson's correlation coefficient and the intraclass correlation coefficient may indicate a high degree of correlation between the 2 care settings. However, the possibility remains that there are systematic measurement errors. Prieto et al[15] recommended comparisons using the tests employed here (Student *t* test for paired samples), and when applied in our study those tests revealed clear differences between the 2 care settings. This confirms that a very high percentage of spirometry tests do not meet the reproducibility criteria recommended by the ATS (76% for FVC) and that the error rate for functional diagnosis is 39.7%. As in previous studies, the differences were much more apparent for FVC than for FEV_1. This is explained by failures in the termination of the forced expiratory maneuver—the most frequently detected error in various studies[4,16]; however, in our study, although the differences found in the termination of the maneuver between primary and specialized care settings were substantial, they were even larger when considering the beginning of the maneuver.

It is well known that the training of professionals responsible for performing spirometry represents a decisive factor in the quality of the procedure. In an effort to improve the level of training, some months before the beginning of the second part of the study the department responsible for primary care in Navarre had begun a training program for health care center nursing staff; the program consisted of 2 sessions, 1 theoretical and the other practical, provided by pneumologists and trained nurses over a total of 9 hours. A study performed in New Zealand confirmed that training sessions lasting 2 hours led to an increase in the number of correct spirometry tests performed, but the percentage of defective tests remained high.[16] Although our study was not designed to evaluate the training program, the results suggest to us that such programs are inadequate. On the other hand, the system through which personnel are contracted and the possibility of movement in the position held by nursing staff in Spain makes it very difficult to obtain appropriately trained staff with continuity of roles in all health care centers.

In Spain, Plaza et al[17] undertook a study aimed at designing models to improve the relationship between primary care and pneumology specialty departments and showed that spirometry, performed in a centralized outpatient setting and supervised by pneumologists, was the most valued part of the program, even more appreciated than joint clinics or emergency pneumology consultations.

The results obtained in this study indicate that supplying spirometers to health care centers is insufficient for achieving appropriate utilization of spirometry in primary care; that will only be possible if high quality is obtained in the tests performed. Probably, an option to consider is to achieve sufficient availability of centralized outpatient pulmonary function units that are easily accessed and have adequately trained professionals who are specifically dedicated to the task and supervised in some way by pneumologists. Such measures would guarantee the quality of the results obtained by our colleagues in primary care and would undoubtedly play an important role in introducing spirometry definitively in this care setting.

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APPENDIX 1
Spirometry Questionnaire Completed by All Health Care Centers in Navarre (English Translation)

Health Care Center		Number of adult patients:			
Registration number:		Urban or rural?			
Spirometer available	Yes/No				
If yes,	Model:				
Year of purchase:					
Do you know which reference values are used with the spirometer?	Yes/No	Which ones?			
What is the average number of spirometry tests performed in your center over the last 12 months in individuals aged over 14 years?					
0	<5 per week	5-10 per week	10-20 per week	20-30 per week	>30 per week
Are a barometer and thermometer available where spirometry is performed?	Yes/No				
Is a calibration syringe available?	Yes/No				
If yes, is the apparatus calibrated?	Yes/No				
How often?	Daily	Weekly	Monthly	Less than monthly	
Prior to spirometry, are instructions systematically provided to patients to abstain from use of drugs such as bronchodilators that can affect the results of the test?	Yes/No				
Prior to spirometry, is the test systematically explained to patients?	Yes/No				
How many spirometry maneuvers are performed per patient?					
Professional responsible for performing spirometry	Doctor/Nurse				
Is a single professional usually responsible for performing spirometry?	Yes/No				
If not, how often is the task rotated?	Daily	Weekly	Monthly	>Monthly	
Has the individual responsible for spirometry undergone supervized training in its use?	Yes/No				
Where?					
Total number of training hours:					

APPENDIX 2
Assessment of Quality of Spirometry Performed in Primary Care

Health center			Registration number		Date
Age (always >14 y):			Sex:		
Weight:			Height:		Referring doctor:
Educational level	No formal education	Primary education	Secondary education		Higher education
Smoking	Nonsmoker	Active smoker >40 pack-years	Active smoker <40 pack-years	Ex-smoker minimum 6 months >40 pack-years	Minimal ex-smoker 6 months <40 pack-years
Reason for requesting spirometry		Suspicion of COPD	Suspicion of asthma	Unexplained dyspnea	Other
Has the patient previously undergone spirometry in specialized care services?				Yes/No	
Has the patient used bronchodilators since yesterday evening?				Yes/No	
Data on spirometry performed in primary care					
Assessment of flow-volume curve (onset, slope, termination)					
FVC, mL	FVC, %				
FEV_1, mL	FEV_1, %				
FEV_1/FVC %					
Data on spirometry performed in specialist care					
Assessment of flow-volume curve (onset, slope, termination)					
FVC, mL	FVC, %				
FEV_1, mL	FEV_1, %				
FEV_1/FVC %					

COPD indicates chronic obstructive pulmonary disease; FVC, forced vital capacity; FEV_1, forced expiratory volume in the first second.