European Review for Medical and Pharmacological Sciences 2023; 27: 9754-9761

Impact of pre-test information on patient compliance with the spirometry protocol: a randomized controlled clinical trial

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Abstract. – OBJECTIVE: This study evaluated the effect of brochure-based and video-assisted information provided before spirometry on patient compliance.

PATIENTS AND METHODS: This was a randomized controlled clinical trial. Before the test, subjects in intervention groups were shown a leaflet outlining the steps of the spirometry protocol and a video prepared for the same purposes. The control group was given standard routine information by the technician before spirometry.

RESULTS: The study included 450 patients. We found a significant correlation between compliance status and age, female sex, being a non-smoker, having no known lung disease, investigating respiratory disease as an indication for spirometry, having first-time spirometry, and receiving pre-test information *via* leaflets. Variables of age, sex, smoking, indication for spirometry, diagnosis, and previous spirometry, which were found in multivariate analysis to be associated with 'compliance with the test protocol' were further processed using regression analysis which identified 'previous spirometry' as the most decisive variable affecting 'compliance with the test protocol'.

CONCLUSIONS: Providing information *via* brochure-based and video-supported information did not contribute to compliance with the testing protocol, leading us to the conclusion that such informative tools do not provide an additional contribution. Previous spirometry experience was the most decisive parameter influencing adherence to the test protocol.

Key Words:
Patient education, Respiratory function tests, Spirometry, Test failure, Lung function.

Introduction

Spirometry is one of the basic tests used in the diagnosis and monitoring of respiratory diseases, preoperative risk assessment and prognostic evaluation. In order for the test to yield objective results, it must follow international standards and criteria for acceptable quality. In routine practice, the technician first demonstrates the respiratory maneuvers to be performed during testing, and the patient takes the test, but when the patient fails to comply, the test is repeated[1]. The major factor in patient non-compliance is failure to correctly follow the instructions given by the technician[1]. In such cases, the test needs to be repeated.

Since spirometry is performed indoors, repeat testing has been increasingly associated with concerns over COVID-19 transmission, especially during the pandemic. The repeat forced expiration maneuver may result in virus-containing droplets being released into the environment. In the context of anti-COVID-19 measures, guidelines[2] have recommended a maximum of two test repetitions in an attempt to reduce transmission. Ensuring patient compliance with the test protocol can reduce repeat testing and the time spent by the patient at the testing location.

Multimedia-based education is widely used to provide patient information[3] and has gained interest during the pandemic. Video-assisted patient education is used in various areas of healthcare, including successful patient education on inhaler techniques in chronic obstructive pulmonary disease[4] and education on continuous positive airway pressure machines in sleep apnea[5].

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Current guidelines[6] recommend that patients are given an information leaflet before spirometry testing. To the best of our knowledge, based on a literature review, no study has yet investigated the impact of pre-test patient education on compliance with the spirometry protocol. In this context, this study sought to investigate the impact of leaflet-based and video-assisted information provided before spirometry on patient compliance with the test protocol.

Patients and Methods

Participants

The sample consisted of all patients who presented for pulmonary function testing (PFT). The study included 450 patients who presented to the PFT laboratory for spirometry, volunteered to participate in the study, and met the inclusion criteria. Patients were assigned to groups based on lists for simple random sampling using a table of random numbers. Fifty patients who were illiterate and had communicational, hearing, and visual impairments were excluded (Figure 1).

Study Design

This was a randomized controlled clinical trial conducted between December 2021 and December 2022. G-power analysis found that the minimum sample size should be 207 (0.95 power and 0.05 significance level).

Setting

The study was performed at Gaziantep University Pulmonology PFT laboratory using a Vmax-spectra model 29 spirometer. The tests were administered by two certified technicians trained in spirometry, with at least 7 years of experience.

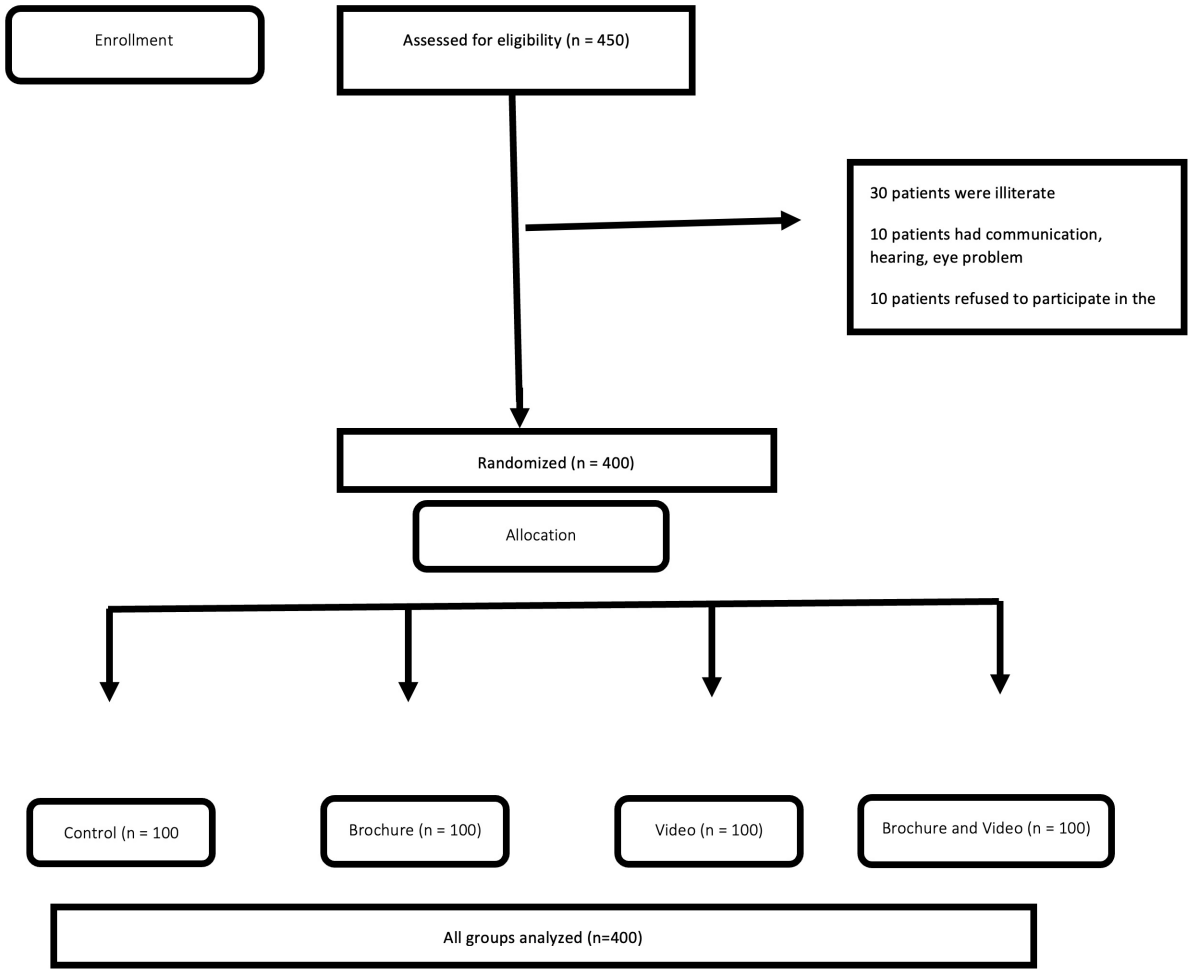

Figure 1. Flow Chart.

Data Collection

The study data were recorded on patient assessment forms. This form included sections related to patient socio-demographic characteristics (age, sex, education, smoking, and comorbidities), diagnosis, indication for referral to the spirometry laboratory, history of previous spirometry, number of previous spirometry tests, compliance with the test protocol and reasons for non-compliance [artifacts (cough, incomplete maximal inspiration and maximal effort, chest pain, leak at the mouth and variable effort), completion of 6 s and fast start to the test][7].

Patients in all groups were supervised by a pulmonologist during the procedure and classified as compliant or non-compliant. In line with the literature, patients were classified as 'compliant' if they had no artifacts, sustained expiration ≥6 s, and time to peak flow <150 ms, while those who did not meet at least one of these criteria were classified as 'non-compliant'[7,8].

Patients who presented for spirometry were informed of the purpose and scope of the study. Those who accepted to participate in the study and met the inclusion criteria were randomly (Randomiser.org) assigned to one of the groups. All subjects were blinded to the randomization procedure; however, the operators were not blinded to the patient groups due to the nature of the intervention. Interviews were conducted in the PFT laboratory *via* face-to-face interviews. At the first interview, patient characteristics were recorded on the patient assessment forms, and the following steps were followed.

Before the test, subjects in intervention groups were shown a leaflet outlining the steps of the spirometry protocol prepared in accordance with the guidelines and a video prepared for the same purposes[7]. The control group was given standard routine information by the technician before spirometry.

Information *via* leaflets: the subjects were given a leaflet prepared by the researchers based on a literature review[7,8]. The leaflet contained written and visual information about the steps of spirometry. The patients then underwent routine spirometry.

Video-assisted education: using a mobile phone, patients were shown a two-minute video prepared by the researchers in accordance with the guidelines[7,8] that demonstrated how spirometry is performed.

Education *via* leaflets + video: subjects in this group were first given a leaflet and shown the video. They later underwent routine spirometry[7,8].

Ethical Aspect of the Research

Informed consent was obtained from all patients before starting the study. Approval was obtained from the Ethics Committee (2021/368) and the study was conducted in accordance with the Declaration of Helsinki.

Statistical Analysis

The data were checked for normality of distribution using the Shapiro-Wilk test. Numerical data for four independent groups were compared using the Kruskal-Wallis' test. Relationships among numerical variables were tested using correlation analysis, and relationships among categorical variables were evaluated using the Chi-square test. Variables found to be significant in basic statistical tests were processed using regression analysis. The data were evaluated using the SPSS 22 (IBM Corp., Armonk, NY, USA) package program. $p<0.05$ was considered statistically significant.

Results

The mean age of the patients was 50±16.9 years, and the majority were women (n=213, 53.3%). Patients presented to the laboratory with no known lung disease (n=228, 57%), asthma (n=107, 26.8%), chronic obstructive pulmonary disease (COPD) (n=31, 8.8%), and other lung diseases (n=30, 7.5%). In most instances, spirometry was indicated for investigating respiratory diseases (n=277, 69.3%). Half of the patients (n=186, 46.5%) who presented for spirometry had not undergone spirometry before. The mean number of tests performed was 4.2±1.4, and the most common reason for "non-compliance" was the failure to maintain blowing for 6 s (n=124, 31%) (Table I).

There was no statistically significant correlation between compliance and the information provided to the patients before the test, age, sex, educational status, smoking, diagnosis, indication for spirometry, previous spirometry, number of previous spirometry tests, and number of repeat tests (Table II).

In order to identify parameters that may be associated with 'compliance with the test protocol', multivariate analysis was performed between 'compliance' and age, sex, education, smoking, diagnosis, indication for spirometry, previous spirometry, number of previous spirometry tests, and type of pre-test information. This analysis found a statistically significant correlation be-

Table I. Demographics, clinical and some spirometric characteristics of patients.

Features		n (%)
Age (mean±SD)	50±16.9 years	400 (100)
Sex	Female	213 (53.3)
	Male	187 (46.8)
Education	No formal education	88 (22)
	Primary	180 (45)
	Secondary	57 (14.2)
	Tertiary	75 (18.8)
Smoking	Smoker	96 (24)
	Former smoker	72 (18)
	Non-smoker	232 (58)
Diagnosis	Asthma	107 (26.8)
	COPD	31 (8.8)
	Other lung disease	30 (7.5)
	No known lung disease	228 (57)
Indication for spirometry	Investigating respiratory disease	277 (69.3)
	Assessing disease severity	123 (30.8)
Previous spirometry	Yes	214 (53.5)
	No	186 (46.5)
Number of previous spirometry tests (Mean±SD)		4.7 (8.7)
Number of repeat tests (Mean±SD)		4.2 (1.4)
Compliance with the test protocol	Compliant	261 (65.3)
	Non-compliant	139 (34.8)
Cause of non-compliance		
Spirometry test artefact	Yes	261 (65.3)
	No	139 (34.8)
Completion of 6 s of spirometry	Yes	124 (31)
	No	276 (69)
Fast start in spirometry	Yes	366 (91.5)
	No	34 (8.5)

*Other lung diseases: obstructive sleep apnea syndrome, sarcoidosis, chronic bronchitis, bronchiectasis, cystic fibrosis, and lung cancer. COPD: chronic obstructive pulmonary disease.

tween compliance status and older age (p=0.01), female sex (p=0.03), being non-smoker (p=0.03), having no known lung disease (p=0.004), investigating respiratory disease as an indication for spirometry (p=0.004), having first-time spirometry (p=0.001) and receiving pre-test information *via* leaflets (p=0.02) (Table III).

Variables of age, sex, smoking, indication for spirometry, diagnosis, and previous spirometry, which were found in multivariate analysis to be associated with 'compliance with the test protocol' were further processed using regression analysis which identified 'previous spirometry' as the most decisive variable affecting 'compliance with the test protocol' (Exb B: 0.34, p=0.001, Nagel kerke: 0.13, Enter method) (Table IV).

Discussion

The present study found that using leaflet, video and leaflet + video for patient education before spirometry had no effect on patient compliance with the test protocol. Compliance with the test was found to be low in older subjects, females, non-smokers, those in whom spirometry was indicated for investigation of respiratory disease, those with no known lung disease, those with no previous spirometry and those who received information *via* leaflets. Previous spirometry was the most decisive independent variable affecting compliance with the test protocol. Patient information has been reported[4,5] to affect test results, patients' skill levels and to improve patient compliance with the test. The impact of patient information has been investigated in different patient groups; video-assisted information on medication use for COPD patients was found[4] to increase inhaler adherence two-fold, and video-assisted education on continuous positive airway pressure for patients with obstructive sleep apnea syndrome was found[5] to increase adherence approximately three times.

Patient education is done using verbal, printed, and multimedia-based techniques, and pre-procedure information is most frequently delivered verbally[9]. The present study found that 71% of the patients in the group that received routine verbal information (control group) complied with the test protocol. Using printed materials for information is known[9,10] to complement verbal information, and leaflets are a common tool used for this purpose[11]. In this study, the group that received information *via* leaflets had lower compliance with the test protocol than those in all the other groups. This may be because most of the patients may not have read the leaflet. A study[12] conducted with pharmacy students reported that compliance was better in the group that received pre-procedure information *via* leaflets compared to those who received routine information provided by the technician. Our study differs from previous studies in the literature because the subjects were mostly elderly individuals and had low education levels.

Our study found that providing video-assisted information had no effect on compliance with the test protocol. Video-assisted education allows the

Table II. Correlation between pre-test information, clinical characteristics and compliance.

	Control, n (%)		Leaflet n (%)		Video n (%)		Leaflet + Video n (%)		*p*-values
	Non-compliant	Compliant	Non-compliant	Compliant	Non-compliant	Compliant	Non-compliant	Compliant	
Age (mean±SD)	53.2±21.4	48.8±14.7	51.5±16.3	51.5±15.6	51.4±16.3	51.4±15.16	50.9±18.8	49.6±16.2	0.6
Sex									0.1
Male	10 (18.2)	40 (30.3)	24 (43.6)	30 (22.7)	8 (1.5)	34 (25.8)	13 (23.6)	28 (21.2)	
Female	19 (22.6)	31 (24)	22 (26.2)	24 (18.6)	20 (23.8)	38 (29.5)	23 (27.4)	36 (27.9)	
Education									0.7
No formal education	3 (11.1)	12 (19.7)	12 (44.4)	14 (23)	4 (14.8)	16 (26.2)	8 (29.6)	19 (31.1)	
Primary Secondary	17 (25.4)	-32.7	22 (32.9)	20 (17.7)	10 (14.9)	37 (32.7)	18 (26.9)	19 (16.8)	
Tertiary and above	4 (21.1)	7 (18.4)	6 (31.6)	11 (28.9	5 (26.3)	8 (21.1)	4 (21.1)	12 (31.6)	
Smoking									0.4
Smoker	3 (12.5)	24 (33.3)	6 (25)	16 (22.2)	9 (37.5)	14 (19.4)	6 (25)	18 (25)	
Former smoker	4 (17.4)	9 (18.4)	11 (47.8)	12 (24.5)	4 (17.4)	17 (34.4)	4 (17.4)	11 (22.4)	
Non-smoker	22 (23.9)	38 (27.1)	29 (31.5)	26 (18.6)	15 (16.3)	41 (29.3)	26 (28.3)	35 (25)	
Diagnosis									0.4
Asthma	2 (7.4)	17 (21.3)	8 (29.6)	17 (21.3)	8 (29.5)	29 (36.3)	9 (33.3)	17 (21.3)	
COPD	5 (55.5)	8 (30.8)	1 (11.1)	5 (19.2)	1 (11.1)	5 (19.2)	2 (22.2)	8 (30.8)	
Other lung disease	3 (27.3)	7 (36.8)	3 (27.3)	1 (5.3)	3 (27.3)	3 (15.8)	2 (18.2)	8 (42.1)	
No known lung disease	19 (20.7)	39 (28.7)	34 (37)	31 (22.8)	16 (17.4)	35(25.7)	23 (25)	31 (22.8)	
Indication for spirometry									0.2
Investigating respiratory disease	21 (19.3)	49 (29.2)	38 (34.9)	37 (22)	24 (22)	43 (25.6)	21 (19.3)	49 (29.2)	
Assessing disease severity	8 (26.7)	22 (23.7)	8 (26.7)	17 (18.3)	4 (13.3)	29 (31.2)	8 (26.7)	22 (23.7)	
Previous spirometry									0.11
No	17 (19.1)	28 (28.9)	37 (41.6)	22 (22.7)	14 (15.7)	31 (32)	21 (23.6)	16 (16.5)	
Yes	12 (24)	43 (26.2)	9 (18)	32 (19.5)	14 (28)	41 (25)	15 (30)	48 (29.3)	
Number of previous spirometry tests (mean±SD)	0.89±1.9	2.94±4.8	1.6±5.1	2.0±4.0	2.5±6.7	2.43±4.3	1.5±5	4.46±13.1	0.19
Number of repeat tests (mean±SD)	4.5±1.5	4.16±1.5	4.3±1.3	4.16±1.5	4.7±1.6	4.28±1.2	4.3±4.9	3.8±1.17	0.35

patient to receive information in a non-clinic setting without the risk of transmission. This technique is especially suitable for individuals with low levels of education[13]. Akuthota et al[14] reported that video-assisted education achieved rates of success similar to verbal information. Another study[15] found that the use of video-assisted education on inhaler use among children significantly improved skills in inhaler technique. The reason why video-assisted information failed to lead to better results in our study is that it was provided only once. Indeed, in order for information to lead to expected outcomes, it may need to be provided several times. Baba et al[16] reported that

Table III. Correlation between clinical characteristics and compliance with the test protocol

Features		Non-compliant n (%)	Compliant n (%)	*p*-values
Age (Mean±SD)		51.7±19.6	50.3±15.3	0.01
Sex				0.03
	Male	55 (39.6)	132 (50.6)	
	Female	84 (60.4)	129 (49.4)	
Education				0.58
	No formal education	29 (20.9)	59 (22.6)	
	Primary education	69 (49.6)	111 (42.5)	
	Secondary education	18 (12.9)	39 (14.9)	
	Tertiary education and above	23 (16.5)	52 (19.9)	
Smoking				0.03
	Smoker	24 (17.3)	72 (27.6)	
	Former smoker	23 (16.5)	49 (18.8)	
	Non-smoker	92 (66.2)	140 (53.6)	
Diagnosis	0.004			
	Asthma	27 (19.4)	80 (30.7)	
	COPD	9 (6.5)	26 (10)	
	Other lung disease	11 (7.9)	19 (7.3)	
	No known lung disease	92 (66.2)	136 (52.1)	
Indication for spirometry				0.04
	Investigating respiratory disease	109 (78.4)	168 (64.4)	
	Assessing disease severity	30 (21.6)	93 (35.6)	
Previous spirometry				0.01
	No	89 (64)	97 (37.2)	
	Yes	50 (36)	164 (62.8)	
Numbers of previous spirometry tests (Mean±SD)		4.5 (7.5)	4.7 (9.1)	0.06
Pre-test education				0.02
	Control	29 (20.9)	71 (27.2)	
	Leaflet	46 (33.1)	54 (20.7)	
	Video	28 (20.1)	72 (27.6)	
	Leaflet + video	36 (25.9)	64 (24.5)	
	Control	29 (20.9)	71 (27.2)	

COPD: Chronic obstructive pulmonary disease.

53.6% of patients misused the inhaler after the first information session, and 48.8% continued to misuse the device even after the third information session. Takaku et al[17] reported that 59% of the patients misused the inhaler after the first information session and that at least three training sessions are needed to reduce the rate of misuse to 10%. Another study[18] showed that device use education had a positive effect on patients' ability to use the device.

There are conflicting results in the literature with respect to the association between age and compliance with the test protocol. Melo et al[19] reported a spirometric performance rate of 87.6% among the elderly subjects, while another study[6] reported a rate of 92.6%. Pezzoli et al[20] reported a performance rate of 81.8% among 715 elderly patients. Enright and Lehmann[21] reported that younger subjects had better compliance with the spirometry protocol. The present study found lower compliance among elderly patients. This difference may be attributed to the use of different criteria for compliance definition and different limits for age classification.

Limitations

This study has the following limitations: information was provided only once, and the results of the study included data from a single center.

Table IV. Logistic regression analysis of variables associated with "compliance with the test protocol".

Feature	B	S.E.	df	Sig.	Exp (B)	95% CI for EXP (B) Lower	Upper
Age	-.005	.007	1	.42	.99	.98	1.00
Sex (Males as reference)	-.38	.26	1	.15	.68	.40	1.15
Smoking (Non-smokers as reference)			2	.13			
Smokers	.61	.31	1	.04	1.85	1.00	3.42
Former smokers	.21	.34	1	.53	1.23	.62	2.44
Indication for spirometry (assessing disease severity as reference)	-.29	.31	1	.35	.74	.40	1.37
Diagnosis (no known lung disease as reference)			3	.73			
Asthma	.20	.34	1	.55	1.20	.62	2.38
COPD	-.27	.49	1	.58	.76	.28	2.00
Other lung diseases	-.13	.43	1	.75	.87	.37	2.04
Those with previous spirometry as reference	-1.05	.25	1	.001	.34	.21	.57
Constant	1.65	.51	1	.001	5.20		

COPD: chronic obstructive pulmonary disease.

Conclusions

Our study is the first randomized controlled trial to investigate the effect of leaflet-based and video-assisted information on compliance with the spirometry protocol. Previous spirometry was the most decisive parameter affecting compliance with the test protocol. Providing information *via* brochure-based and video-supported information did not contribute to compliance with the testing protocol, leading us to the conclusion that such informative tools do not provide an additional contribution. Further studies are needed to investigate different techniques that can improve compliance with test protocols.

Conflict of Interest

The authors declare that they have no conflict of interest.

Acknowledgments

The authors are grateful to the anonymous reviewers for their comments, which have helped to improve the paper. We thank our Spirometry technicians Ayşegül Kahraman and İbrahim Alyaz for their contributions.

Informed Consent

Patients and/or their families signed informed consent forms.

Availability of Data and Materials

The data that support the findings of this study are available from the Corresponding author but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are, however, available from the authors upon reasonable request and with permission of Gaziantep University, Sahinbey Research and Application Hospital.

Authors' Contributions

SD: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Project administration. SA, SAAAL: Methodology, Formal analysis, Writing – review & editing. ÖO, CS, MT: Conceptualization, Methodology, Formal analysis, Writing – review and editing, Supervision. MU: Conceptualization, Methodology, Formal analysis, Writing – review and editing, Supervision.

Funding

This study received no funding.

Clinical Trial Registration Number

Thi trial has been registered on clinicaltrials.gov (NCT05921630)

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