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Quality of spirometry in the elderly

Jakość badania spirometrycznego u osób w podeszłym wieku

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Abstract

Introduction: Spirometry is the basic method used to diagnose and monitor obstructive diseases. Spirometric tests are performed in more and more people of advanced age (more than 65 years old). The objective of the study was to assess the quality of spirometry (measurement of the flow-volume curve) in subjects of the aforementioned age group, with reference to applicable quality criteria specified in guidelines ERS/ATS 2005 and PTChP 2006.

Material and methods: The study was of a retrospective nature. The authors analysed the results of spirometry performed in 1271 subjects who were 65 to 94 years old and who underwent spirometric tests in the Respiratory Physiopathology Laboratory of Kujawy-Pomorze Regional Centre of Pulmonology in Bydgoszcz over a period of 6 months. This group included 759 males (average age 73.2 $\pm$ 5.9 years) and 512 females (average age 73.2 $\pm$ 5.7 years). The quality of the spirometry was assessed according to error codes assigned to individual spirometric sessions by the software JLab 5.31 installed in the measuring system MasterScreen (CareFusion).

Results: Twenty-nine (2.3%) of the 1271 subjects failed to perform spirometric measurements. For the remaining 1242 subjects the following spirometry quality was determined: correctly performed spirometric test in 415 (33.4%) subjects; one error in 673 (54.2%) subjects; 2 errors in 136 (11%) subjects; 3 errors in 15 (1.2%) subjects and 4 errors in 3 (0.2%) subjects. The analysis of individual errors revealed that the lack of a *plateau* at the end of exhalation was found in 747 (60.1%) subjects (including only 25 (2%) subjects with FET $<$ 6 s); increased BEV value in 7 (0.6%) subjects; abruptly finished exhalation in 36 (2.9%) subjects; and no FVC and FEV_1 repeatability in 43 (3.5%) and 169 (13.6%) subjects, respectively.

Conclusions: The most common error was the lack of a *plateau* at the end of exhalation. Therefore, paying particular attention to the final phase of exhalation during spirometry should, as a result, increase the percentage of correctly performed spirometric tests in the elderly.

Key words: spirometry, quality control, elderly, lung function

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Streszczenie

Wstęp: Spirometria jest podstawową techniką wykorzystywaną w diagnozowaniu i monitorowaniu chorób obturacyjnych. Coraz większą grupę objętą badaniami spirometrycznymi stanowią osoby w wieku podeszłym, które ukończyły 65. rok życia.
Celem pracy była ocena jakości wykonania spirometrii (pomiaru krzywej przepływ–objętość) u osób w tej grupie wiekowej w odniesieniu do obowiązujących kryteriów jakościowych zdefiniowanych w zaleceniach ERS/ATS 2005 i PTChP 2006.

Materiał i metody: Badanie miało charakter retrospektywny. Przeanalizowano wyniki badań spirometrycznych 1271 osób w wieku 65–94 lata, którym wykonano spirometrię w Pracowni Fizjopatologii Oddychania Kujawsko-Pomorskiego Centrum Pulmonologii w Bydgoszczy w ciągu 6 miesięcy. W tej grupie było 759 mężczyzn (śr. wiek: 73,2 $\pm$ 5,9 roku) oraz 512 kobiet (śr. wiek: 73,2 $\pm$ 5,7 roku). Oceniano wykonanie spirometrii na podstawie analizy kodów błędów przypisywanych sesji spirometrycznej przez oprogramowanie JLab 5,31 systemu pomiarowego MasterScreen (CareFusion).

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Wyniki: Spośród 1271 osób spirometrii nie wykonało 29 badanych (2,3%). U pozostałych 1242 osób stwierdzono: bezbłędnie wykonaną spirometrię u 415 (33,4%); jeden błąd u 673 (54,2%); 2 błędy u 136 (11%); 3 błędy u 15 (1,2%) i 4 błędy u 3 osób (0,2%). Analizując poszczególne błędy, stwierdzono: brak *plateau* na końcu wydechu u 747 (60,1%) (w tym jedynie 25 — 2% badanych miało FET < 6 s), zbyt dużą wartość BEV u 7 (0,6%) osób; gwałtowne zakończenie wydechu u 36 (2,9%); brak powtarzalności FVC u 43 (3,5%) i FEV_1 u 169 (13,6%) badanych.

Wnioski: Najczęściej występującym błędem było nieosiąganie *plateau* na końcu wydechu. Dlatego zwrócenie szczególnej uwagi na końcową fazę wydechu w czasie badania powinno przyczynić się do zwiększenia odsetka prawidłowo wykonanych spirometrii u osób w podeszłym wieku.

Słowa kluczowe: spirometria, kontrola jakości, wiek podeszły, funkcja płuc

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Introduction

Spirometry is the basic tool for lung function assessment, useful for the diagnosis and monitoring of respiratory diseases, especially obstructive ones. The recommendations concerning these diseases (GOLD [1], PTChP [2], GINA [3]) clearly indicate the significant role of spirometry in the diagnosis and monitoring of COPD, and its auxiliary role in the diagnosis of asthma. The evaluation of lung function is also important to determine therapeutic strategy. It also plays a crucial role in disability adjudication.

Standards for performing spirometry have been established for many years. The first document was drawn up in 1965 by experts from the International Labour Organization [4], and the first standardization by ATS was published in 1979 [5]. A similar initiative was taken by the European Community for Coal and Steel (ECCS) in 1983 [6]. Then, scientific societies such as ATS (1987, 1994), ERS (1993) and BTS [7–10] published their own recommendations. In 2005 a global standard document was published by ERS and ATS [11, 12]. Polish "Guidelines for spirometry performance" were published for the first time in 2004, and updated in 2006 [13, 14].

Current recommendations clearly determine quality criteria for spirometric measurements, particularly for the flow-volume curve, which is used to calculate FEV_1 (forced expiratory volume in 1 second) and FVC (forced vital capacity) values, essential for interpretation of changes in the respiratory system. According to these recommendations, only results that meet defined quality criteria may be interpreted.

Standardized recommendations distinguish two groups of patients in respect of cooperation during spirometry: young children and the elderly. Problems connected with incomprehension of procedures, inappropriate cooperation, fear of the examination or reluctance to perform it may occur in both groups. Qualitative analysis concerning children less than 10 years of age was published in 2008 [15], and it showed that approximately 1/3 of children are able to perform spirometry correctly.

According to the World Health Organization (WHO), old age may be divided into three periods: advanced age (from 60 to 75 years), old age (from 75 to 90 years) and ripe old age (from 90 years). Chronological age does not always correspond to biological age, and there is no agreement between researchers regarding when old age begins. Sometimes it is considered to be 65 years of life but more frequently 70.

The pace of ageing of Polish society is rapid. According to the Central Statistical Office (Główny Urząd Statystyczny — GUS, December 2005), there live about 5.1 million people aged 65 years and over in Poland, which constitutes more than 13% of the population (every 8th citizen). It is expected that in 2030 this proportion will reach 21.1%. Similar tendencies are observed in many countries [16–18].

The elderly constitute a specific group. The widespread occurrence of COPD and asthma [19, 20], which are frequent causes of morbidity and mortality among ageing people [21–23], and the prevalence of accompanying conditions with similar symptoms leading to diagnostic errors, are reasons for the need for more frequent testing than in other age groups. On the other hand, degenerative processes and diseases connected with old age may cause difficulties in understanding the procedures and cooperating with the staff performing spirometry.

The aim of the study was to assess spirometry quality (measurement of the flow-volume curve) and to analyse errors reported by the MasterScreen measuring system during spirometry in subjects 65 years of age and older, with reference to the quality criteria defined in recommendations by ERS/ATS of 2005 and PTChP of 2006.

Material and methods

The study was retrospectively designed. For the purposes of the study, among all the 3008 spirometry tests performed in the Respiratory Physiopathology Laboratory of the COPD Centre and Respiratory Failure of the Kujawy-Pomorze Regional Centre of Pulmonology in Bydgoszcz in the period from June 2010 until January 2011, spirometry test results of subjects aged ≥ 65 years were analysed. The group included 1271 persons (42.3% of all studied subjects) aged 65-94 years (mean age 73.20 ± 5.90 years): 759 males (mean age 73.2 ± 5.9 years) and 512 females (mean age 73.2 ± 5.7 years). The most frequently diagnosed diseases were COPD and asthma.

The measurements of VC and the flow-volume curve were performed by 4 experienced nurses in accordance with guidelines laid out by ERS/ATS in 2005 and PTChP in 2006. The nurses had 5–10 years' experience in performing spirometry tests. The Laboratory performs about 7000 tests per year. For the two former months the tests were performed using a new MasterScreen device, CareFusion, USA. The staff participated in training about correct performance and interpretation of spirometry and advanced training conducted by the Polish Respiratory Society (Polskie Towarzystwo Chorób Płuc — PTChP), as well as the training organized as part of clinical trials, and internal training conducted by an expert in lung diseases, experienced in performing spirometry. The device (MasterScreen, CareFusion, USA) was calibrated every day before the tests with the use of a 3-litre calibration syringe. Before the test, each patient was precisely informed about the spirometry procedure. Spirometry was performed in a sedentary position, in accordance with the standard [12, 14]. In order to obtain three acceptable and repeatable curves, each patient had from 3 to 8 FVC measurements taken.

The JLab 5.31 software from MasterScreen marks each manoeuvre with quality codes according to the ATS/ERS criteria of 2005; in cases when a manoeuvre does not meet the quality criteria, an error code indicates the problem.

Table 1 includes error codes and corresponding messages and definitions.

When more than one error occurs, the system combines error codes, so the code 4102 means the error 2, 100 and 4000. With such a standardized description of spirometry, quality errors 1 and 10 mean *de facto* failure to perform the spirometry test (spirometry cannot be interpreted). In the remaining cases spirometry is technically incorrect (manoeuvres are not accepted technically), but the examination may be assessed.

Table 1. Error codes of spirometric test performance by ERS/ATS 2005

Tabela 1. Kody błędów wykonania badania spirometrycznego wg ERS/ATS 2005

Error code	Description
1	Less than 3 attempts
2	Not meet the criteria for repeatability FVC — the two highest FVC values differ by more than 150 mL
4	Not meet the criteria for repeatability FEV_1 the two highest FEV_1 values differ by more than 150 mL
10	Changeable cooperation or lack of cooperation
100	Lack of plateau in the expiratory part of the volume-time curve — during the last second the change of volume > than 25 mL or FET < 6 s
1000	Too high value of back-extrapolated volume BEV (>150 mL or 5% of FVC)
4000	Abrupt end — sharp drop of the flow to 0 — stopping the expiration because of pulling the mouthpiece out or squizzing the mouthpiece or glottis closure

Abbreviations in the text

Results

Among the 1271 examined patients whose results were analysed, 29 subjects (2.3%) failed to perform spirometry due to lack of cooperation during the examination (error 1 — 26 patients, error 10 — 8 patients; in some patients both errors occurred). Spirometry results of 1242 patients were analysed in respect of quality in 740 males (mean age 73.13 ± 5.62 years) and in 502 females (mean age 73.77 ± 6.02 years). An airway obstruction was found in 895 (72%) subjects, results within the norm in 310 (25%) subjects and suspected restriction in 37 (3%) subjects. Characteristics of the subjects are presented in Table 2.

Spirometry was performed correctly by 415 patients (33.4%). One error was found in 673 (54.2%) patients, 2 errors in 136 (11%) patients, 3 errors in 15 (1.2%) patients and 4 errors in 3 (0.2%) patients. Figure 1 shows the proportional distribution of errors in the study group.

The number of errors made (from 0 to 4) did not depend on the age of the subjects. Females performed spirometry better than males. Spirometry was performed correctly by 42.6% of females and 27.2% of males ($p < 0.0001$), whereas the prevalence of 1, 2 and 3 errors was significantly higher in males ($p < 0.0001$).

Table 3 shows the distribution of the occurrence of errors in the whole group depending on age and sex.

Table 2. Characteristics of the subjects

Tabela 2. Charakterystyka badanych

The examined parameter	Description
Age (mean ± standard deviation)	73.15 ± 5.79 lat/years
Sex	
Males (n,%)	740 (59.6%)
Females (n,%)	502 (40.4%)
BMI (mean ± standard deviation)	27.7 ± 5.85
BMI < 30 [kg/m^2]	844 (68%)
BMI ≥ 30 [kg/m^2]	398 (32%)
FVC [L]	2.87 ± 0.93
FVC%	99.2 ± 24.2
FEV_1 [L]	1.60 ± 0.74
FEV_1 (%)	70.9 ± 28.2
FEV_1/FVC (%)	55.2 ± 15.4
Spirometry	
Normal	310 (25%)
Obstruction	895 (72%)
Suspected restriction	37 (3%)

Abbreviations in the text

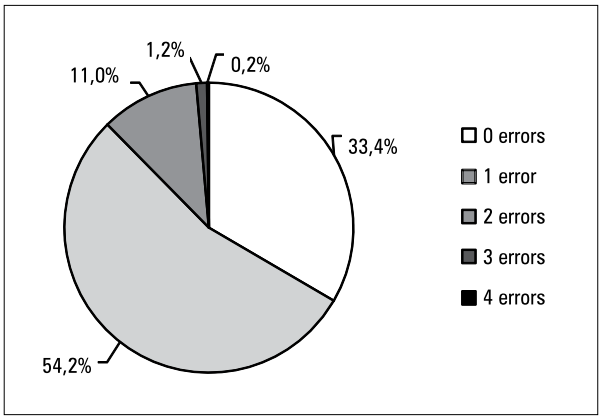

Figure 1. Proportional distribution of errors in the analysed group

Rycina 1. Procentowy rozkład występowania błędów w analizowanej grupie

During spirometric measurements the following errors were found: error 2 in 43 subjects, error 4 in 169 subjects, error 100 in 747 subjects (including FET < 6 s found in 25 (2%) subjects), error 1000 in 7 subjects and error 4000 in 36 subjects. There was no influence of age on the prevalence of individual errors. It was revealed that errors coded by 2 (lack of repeatability of FVC), 4 (lack of repeatability of FEV_1) and 100 (lack of *plateau* in the expiratory part of the volume-time curve) occurred significantly more often in males than in females ($p < 0.0001$). The distribution of the errors in the whole group and their relation to age and gender are presented in Table 4.

The relationship between the errors and the spirometry test results was variable (Table 5). Lack of the repeatability of FVC, abruptly finished exhalation, and FET < 6 s (error 2, 4000 and 100, respectively) were significantly more frequent in patients with suspected restriction than in patients with obstruction or a correct test result. However, lack of *plateau* (error 100) occurred less often in this group than in patients with airway obstruction or with normal test result.

The most common (60.1%) was error 100. This code means lack of *plateau* in the expiratory part of the volume-time curve (change of volume > than 25 mL during the last second) or FET < 6 s (which concerned just 25 (2%) tests). Among the 747 spirometry tests marked by error 100 forced exhalation time (FET) > 6 s was found in 722 cases (96.7%), whereas among the 1242 analysed spirometry tests, FET > 6 s was obtained in 1217 patients (98%). Mean FET was 11.35 ± 3.96 seconds. FET > 15 s was found in 90 (7.2%) subjects with lack of *plateau*, 88 of them were diagnosed with bronchial obstruction, and their mean FET was 17.01 ± 1.92 s. Lack of *plateau* coexisted with 74.4% of results with error 2 (lack of repeatability of FVC). In 607 (48.9%) of subjects

Table 3. Distribution of error prevalence within the entire group of subjects and dependence on age and sex

Tabela 3. Rozkład występowania liczby błędów w całej grupie oraz zależnie od wieku i płci

Number of errors	All subjects (n = 1242)		Age < 75 years (n = 741)		Age ≥ 75 years (n = 501)		p	Males (n = 740)		Females (n = 502)		p
	n	%	n	%	n	%		n	%	n	%	
0	415	33.4	242	32.7	173	34.5	NS	201	27.2	214	42.6	< 0.0001
1	673	54.1	405	54.7	268	53.5	NS	424	57.3	249	49.6	< 0.008
2	136	11	81	10.9	55	11.0	NS	100	13.5	36	7.2	< 0.0003
3	15	1.2	10	1.3	5	1.0	NS	13	1.8	2	0.4	0.03
4	3	0.2	3	0.4	0	0.0	NS	2	0.3	1	0.2	NS

NS — not significant

Table 4. The prevalence of individual error types within the entire group of subjects and dependence on the age and sex

Tabela 4. Występowanie poszczególnych błędów w całej grupie oraz zależnie od wieku i płci

Type of error	All subjects (n = 1242)		Age < 75 years (n = 741)		Age ≥ 75 years (n = 501)		p	Males (n = 740)		Females (n = 502)		p
	n	%	n	%	n	%		n	%	n	%	
Lack of errors	415	33.4	242	32.7	173	34.5	NS	201	27.2	214	42.6	< 0.0001
Error 2	43	3.5	29	3.9	14	2.8	NS	38	5.1	5	1.0	< 0.0001
Error 4	169	13.6	101	13.6	68	13.6	NS	119	16.1	50	10	< 0.0001
Error 100												
Lack of *plateau*	747	60.1	456	61.5	291	58.1	NS	489	66.1	258	51.4	< 0.0001
FET < 6 s	25	2	17	2.3	8	1.6	NS	12	1.6	13	2.6	NS
Error 1000	7	0.6	7	0.9	0	0.0	0.03	4	0.5	3	0.6	NS
Error 4000	36	2.9	16	2.2	20	4.0	NS	21	2.8	15	2.8	NS

FET — forced exhalation time; NS — not significant

Table 5. Prevalence of errors depending on the type of spirometry results

Tabela 5. Występowanie rodzaju błędów zależnie od wyniku w spirometrii

Type of disorder		Lack of errors	Error 2	Error 4	Error 100				FET > 6 s	Error 1000	Error 4000
					Lack of *plateau*	FET < 6s	Lack of *plateau* with FET < 6 s	Lack of *plateau* with FET > 6 s			
Normal (n = 310)	n	146	11	31	133	8	8	125	302	6	16
	%	47.1	3.5	10	42.9	2.6	2.6	40.3	97.4	1.9	5.2
Obstruction (n = 895)	n	244	29	134	604	11	11	593	884	0	16
	%	27.3	3.2	15	67.5	1.2	1.2	66.3	98.8	0	1.8
Suspected restriction (n = 37)	n	24	3	4	11	6	6	5	31	1	4
	%	64.9	8.1	10.8	29.7	16.2	16.2	13.5	83.8	2.7	10.8
Analysed tests (n = 1242)	n	415	43	169	747	25	25	722	1217	7	36
	%	33.4	3.5	13.6	60.1	2	2	58.1	98	0.6	2.9

FET — forced exhalation time

lack of *plateau* was the only error; 591 (47.6%) of them had FET > 6 s.

Figure 2 shows compatibility with criteria recommended by ATS/ERS 2005 and PTChP 2006 guidelines [12, 14]. The best results of acceptability were obtained for the fulfilment of the back-extrapolated volume (BEV) criterion: 1235 (99.4%) tests included at least 3 curves with BEV < 150 mL or 5% of FVC. Mean BEV was 0.06 ± 0.04 mL. Among the criteria for the end of the test, the least satisfying results concerned the *plateau* in the expiratory part of the volume-time curve (change of volume < than 25 mL during 1 second): 495 (39.9%) acceptable tests (i.e. with at least three curves with a period of minimal stabilization 1 second — *plateau*). The percentage of repeatable tests was 96.5% for FVC and 86.4% for FEV_1.

Discussion

In the interpretation of spirometry results, their quality plays a crucial role. Interpretation of an incorrectly performed test could result in considering a healthy person as a sick one, or a sick person as a healthy one, which in turn could result in incorrect diagnostic and therapeutic decisions important to the health of the studied subject. Therefore, attention to the quality of measurements taken should be given high priority in laboratories where spirometry is performed. In order to perform spirometry correctly, cooperation between the patient and technician/nurse who carries out the test is absolutely vital.

The tests carried out on a large group of 18,000 patients of different ages by highly experienced tech-

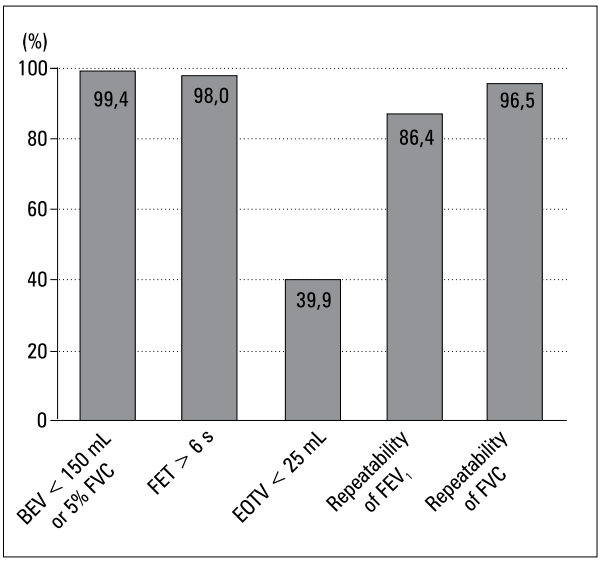

Figure. 2. Meeting of the individual acceptability and repeatability criteria acc. ERS/ATS 2005 [12] and PTChP 2006 [14]. Explanations and definitions of abbreviations: BEV — back-extrapolated volume (acceptable if < 150 mL or 5% of FVC); EOTV — end-of-test-volume (acceptable if during the last second there is no change of volume > than 25 mL); FET — forced exhalation time (acceptable if lasts longer than 6 s); repeatability of FEV_1 — if the difference between the two highest FEV_1 was smaller than 150 mL, repeatability of FVC — if the difference between the two highest was smaller than 150 mL

Rycina 2. Zgodność z poszczególnymi kryteriami akceptowalności i powtarzalności wg ERS/ATS 2005 [12] i PTChP 2006 [14]. Określenia i definicje skrótów: BEV — wstecznie ekstrapolowana objętość (akceptowalna, jeśli < 150 ml lub 5% FVC); EOTV — plateau na części wydechowej krzywej V-T (akceptowalne, jeżeli w ciągu ostatniej sekundy nie ma zmiany objętości > niż 25 ml); FET — czas forsownego wydechu (akceptowalny, jeśli trwa dłużej niż 6 s); powtarzalność FEV_1 — jeżeli różnica między największym FEV_1 i drugą co do wielkości FEV_1 była mniejsza niż 150 ml, powtarzalność FVC — jeżeli różnica pomiędzy największą i drugą największą FVC była mniejsza niż 150 ml

nicians of Mayo Clinic (Rochester, USA) [24] showed that the criteria of acceptability and repeatability were met by 9 out of 10 patients. However, older patients fulfil these criteria with difficulty [25–28].

In the analysed group, technically correct spirometry was performed by 33.4% of patients, which, in comparison with the available data, is a better result. In the study by Pezzoli et al. [25], conducted at a geriatric department on a group of 715 patients aged > 65 years, spirometry was performed correctly by 118 (16.5%) patients, and in the study by Sherman et al. it was performed correctly only by 9 out of 57 patients (15.8%) [26]. In the Polish study [27] conducted on a small group of 47 patients aged > 80 years, this proportion was 11%. De Filippi et al. showed that among 265 patients aged 65–97 years (mean age 80.2 ± 6.8 years), only 53 persons were able to perform spirometry [28]. However, it should be emphasized that the quoted studies were performed in geriatric departments, where understanding of the problem and the ability to cooperate may be lower than among patients staying at the department of lung diseases and pulmonological outpatient clinic.

In the aforementioned studies [25–28] and in the present study, error 100 was the most frequent. It means the lack of a *plateau* in the expiratory part of the volume-time curve (change of volume > 25 mL during the last second) or FET < 6 s. In the present study FET < 6 s concerned only 25 (2%) tests, but lack of *plateau* occurred in 747 (60.1%) subjects, in patients with bronchial obstruction — 604 (67.5%) subjects. Similar results have been obtained by Bellia et al. [29], who also examined patients with pulmonary diseases, mainly asthma and COPD, at similar age (mean age 73.3 ± 5.9 years) — a *plateau* was found in 40.5% of patients, so lack of *plateau* occurred in 59.5% of patients.

According to the present study, females performed the spirometric test better than males. Similarly to the study by Pezzolli et al. [25], there was no difference in age between the patients who were able and those who were not able to perform spirometry in accordance with the guidelines.

According to Enright and Lehmann [30], the following factors influence a correctly performed spirometry in the elderly:
— the ability of the technician/nurse who carries out the test,
— female sex,
— younger age,
— better mental state,
— lack of obesity,
— higher education,
— lesser sensation of dyspnoea,
— greater vitality.

The above list also indicates potential sources of error in the tests of elderly patients. The source of technical errors [30] that result in lack of acceptability of manoeuvres are:
— poorly educated/inexperienced technicians and nurses who perform the test,
— impatient technician/nurse,
— respiratory manoeuvres not demonstrated,
— weak coaching during manoeuvres of deep inhalation/exhalation.

After analysis of the above list, the errors may be divided into two groups: first — errors that depend on the involvement of the person performing the test (error 100 — resulting from insufficient instructions and/or lack of control or coaching during the manoeuvre), and second — errors 2, 4 and 4000 which may be the result of deficient cooperation, indirectly connected also with the cognitive abilities of patients at advanced age.

However, as it was shown in the present study, the most frequent error was lack of *plateau* at the end of exhalation, which was observed in 747 patients (60.1%). This error is the fault of persons who perform spirometry. Although, when metrological criteria and parameters of the device (the screen) that define volume resolution [14] at the level of 50 mL with a minimal scale of the screen 5 mm/L, are taken into account, the lack of *plateau* may not be registered. On the other hand, it is curious that when using current criteria of EOT, in 7% of cases the test was assumed to be incorrect due to one error: lack of *plateau* with forced exhalation time (FET) longer than 15 seconds. The remaining errors concerning acceptability criteria were less common, and their proportion did not exceed 4%.

Therefore, the only way to improve the quality of performed spirometry is constant training and control of the staff who perform the tests. Periodically conducted analyses may allow problems to be identified, assess quantitative proportion of errors and, due to feedback regarding the results of analyses given to persons who perform spirometry, influence improvement of the situation. Such suggestions are included in standardized recommendations.

Conclusions

The most frequent error in elderly patients was lack of *plateau* at the end of exhalation.

Lack of *plateau* occurred more frequently in patients with bronchial obstruction than in patients with suspected restriction or a correct test result.

In more than 7% of cases the only error was lack of *plateau* with a coexistent FET > 15 s.

The number of errors and their prevalence did not depend on the age of patients.

Females performed spirometry better than males.

It seems that regular analysis and control of spirometry performance may increase the proportion of spirometry tests that meet all quality criteria.

Conflict of interest

The authors declare no conflict of interest.

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