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Assessment of peak inspiratory flow in patients with chronic obstructive pulmonary disease: a multicentre, observational, prospective, real-life study

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ABSTRACT

Introduction Patients with chronic obstructive pulmonary disease (COPD) use dry powder inhalers (DPIs) for disease management. DPI effectiveness relies on the patient's peak inspiratory flow (PIF), which may not always be optimal. We conducted an observational multicentre, prospective, real-life cohort study to determine the prevalence of suboptimal PIF in patients with COPD.

Methods 415 participants (11%, n=47 women, mean age=70±8.7 years, mean forced expiratory volume in 1 s (predicted %)=48.1%) recruited from 17 international centres had baseline PIF recorded with an In-Check Dial device at three resistance levels: (1) low, (2) high and (3) the participant's maintenance device. We also recorded PIF from participants as they would do at home to verify their proper inhalation technique. Participants underwent spirometry and completed questionnaires (COPD Assessment Test (CAT), Test of Adherence to Inhalers (TAI)-12).

Results Of the 415 participants, 18% of DPI users (n=75) exhibited suboptimal values of PIF (as typical PIF <than what was required for tested inhalers in the study) when evaluated across DPI resistance groups ranging from low (R1) to high (R5) resistance, compared with 14% of participants (n=60) using devices without resistance (R0). Additionally, 14% of study participants were incapable of producing an optimal PIF or unwilling to do so (27%), impacting medication effectiveness. Participants with suboptimal PIF values had higher mean total CAT score (17.7±7) compared with those with optimal PIF values (12.1±7.6). When assessed globally, 37% (n=56) of participants with suboptimal PIF values did not adhere to treatment, highlighting the need for improved patient education and support.

Conclusion Suboptimal PIF is common in COPD, requiring regular assessment and tailored inhalers.

Trial registration number NCT04606394. Encepp EUPAS34689.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Previous research emphasises the critical role of selecting suitable inhaler devices tailored to the specific needs and abilities of patients with chronic obstructive pulmonary disease (COPD). Factors such as peak inspiratory flow (PIF) and dry powder inhaler (DPI) characteristics are integral to selecting appropriate inhaler devices for COPD management.

WHAT THIS STUDY ADDS

⇒ This study contributes by assessing the prevalence of PIF among patients with COPD worldwide who use DPIs across various internal resistance levels (from R0 to R5), and also provides valuable insights into the clinical implications of PIF in COPD management. By analysing real-world data from a diverse cohort, it enhances our understanding of the difficulties patients with COPD encounter in achieving optimal inhalation technique, emphasising the need for personalised interventions to enhance treatment outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study's findings could influence research by prompting further investigation into personalised interventions to optimise inhaler therapy for patients with COPD, focusing on factors such as PIF and device characteristics. In practice, healthcare professionals may use these insights to tailor treatment plans, selecting the most suitable inhaler devices based on individual patient needs and abilities. Additionally, policymakers might consider incorporating guidelines for PIF assessment into clinical practice to ensure optimal management of COPD and improve patient outcomes.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is the third leading cause of mortality worldwide, with almost 6 million global deaths per year.[1] COPD is a persistent and progressive lung disorder characterised by long-term respiratory symptoms and airflow limitation.[2] The mainstay pharmacological treatment of

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patients with COPD is bronchodilator therapy, with long-acting β2-agonists (LABAs) and long-acting muscarinic antagonists (LAMAs), delivered through inhaler devices such as pressurised metered-dose inhalers (pMDIs), dry powder inhalers (DPIs), soft mist inhalers (SMIs) and nebulisers.[3] Each device has unique advantages and disadvantages for inhalation, delivery and efficacy.[4] For instance, pMDIs require coordination of actuation with slow inhalation by the patient to achieve an optimum clinical effect,[5] whereas SMIs slowly deliver the emitted drug and are less dependent on the inhalation method.[6]

In contrast, DPIs are breath-actuated devices that require the patient's inhalation to generate sufficient peak inspiratory flow (PIF) for proper drug delivery. It is essential to overcome DPIs' internal resistance (R) to disaggregate the drug-containing particles and deliver them correctly to the lungs.[7 8] Each DPI has a different internal resistance and formulation and thus a different optimal PIF, that is defined as the maximal airflow (L/min) achieved during a forced inspiratory manoeuvre.[9] When this is examined against the internal resistance of a particular DPI, the minimum PIF required is generally considered >30 L/min, whereas optimal is >60 L/min and sufficient between 30 L/min and 60 L/min, although this is still under debate.[10 11]

The correct use of DPIs mainly requires the generation of forceful and deep inhalation through the device. However, many patients with COPD, particularly elderly patients and those with severe airflow limitation, are often unable to generate sufficient PIF, which causes poor drug delivery and low lung deposition, so patients cannot achieve full clinical benefit.[12] Thus, the clinical effectiveness of delivering drugs to the lungs depends on correctly performing the inhalation manoeuvre and on choosing an appropriate inhaler device. Studies in patients with COPD report that inhaler technique errors related to inspiratory effort in DPI users were quite common and often associated with poor disease outcomes compared with those on pMDIs or SMIs.[13 14]

We conducted a multicentre study across 17 international centres to determine the prevalence of suboptimal PIF and inadequate inhaler choice in patients with COPD. We report the baseline demographics and clinical characteristics of the participants, providing valuable insights into the clinical role of PIF in patients with COPD.

METHODS

Study design and population

This was an observational, multicentre, prospective, real-life cohort study aimed at evaluating the prevalence of suboptimal PIF and inadequate inhaler choice in patients with COPD, and investigating the impact of suboptimal PIF on long-term outcomes (disease exacerbations, hospital admissions, all-cause mortality) over a 1-year follow-up period. The study was conducted in five European (Spain, Malta, Italy, Belgium, Slovenia) and two Asian (South Korea, Singapore) countries.

The study protocols were registered in public databases (ClinicalTrials.gov NCT04606394, Encepp EUPAS34689).

This manuscript describes the results of the baseline visit where patients were included in the study if they fulfilled the following inclusion criteria: (1) patients older than 40 years of age. (2) COPD diagnosed by a postbronchodilator forced expiratory volume in 1 s (FEV_1)/forced vital capacity (FVC) ratio <0.7. (3) Smokers or former smokers of at least 10 pack-years. (4) Stable disease state, and of at least 4 weeks after clinical resolution of an exacerbation. (5) Capable of performing serial lung function tests.

The exclusion criteria were: (1) An exacerbation in the last 4 weeks. (2) A significant concomitant chronic respiratory condition (other than asthma or bronchiectasis). (3) Unable to understand the instructions of the study or fill out the questionnaires. (4) Unwilling to sign the informed consent. (5) Participating in another clinical trial.

Study procedures

The study consisted of a baseline visit and two follow-up visits every 6 months for a complete follow-up of 1 year.

In this manuscript, we describe the characteristics of the population and their PIF at the baseline visit. During this visit, we collected basic demographics (age, sex, weight, height, body mass index (BMI), occupation) and clinical characteristics such as previous exacerbation history, blood biomarkers and COPD phenotypes (such as chronic bronchitis, emphysema, exacerbator and asthma–COPD overlap) alongside spirometry values.

Exacerbations were defined as follows: a moderate exacerbation was considered an acute course of antibiotics or oral steroids for COPD, while a severe exacerbation involved emergency room attendance or hospitalisation for more than 24 hours due to COPD. The number and severity of exacerbations were recorded over the 6 months prior to the visit, using both medical records and patient reports.

Additionally, patients responded to the COPD Assessment Test (CAT) and the Test of Adherence to Inhalers (TAI)-12 to assess adherence to inhaled treatment and identify the type of non-compliance (eg, erratic, deliberate or unconscious).

The performed TAI-12 tests were on two complementary questionnaires where the first 10 questions measured adherence and intensity, while questions 11 and 12, as part of the second questionnaire, specifically evaluated the pattern of non-compliance by scoring 1 to 2 points in each case.[15]

Peak inspiratory flow measurements

All patients undertook PIF measurement using the In-Check Dial version G16 (Clement Clarke International, Harlow, UK). The In-Check Dial device is a specialised PIF metre with disposable mouthpieces and an adjustable dial to simulate the resistance characteristics

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of different types of inhaler devices due to its accuracy (±10% or 10 L/min) and capabilities to measure flows in the range of 15–120 L/min (±10 L/min). Inhaler resistance is divided into six groups with no resistance (R0, simulating pMDIs and SMIs), and low resistance (R1) through to high resistance (R5 for DPIs).

We measured PIF using the In-Check Dial G16 device and at three different resistance levels:

1. Typical PIF at the resistance of the participant's inhaler device.
2. PIF at low resistance.
3. PIF at high resistance.

At each resistance, three PIF measurements were recorded and then used for analysis.

In cases where participants used more than one maintenance inhaler, DPI measurements were prioritised for those using both a pMDI/SMI and a DPI, and for participants using two DPIs with different resistances, measurements were taken at the higher resistance level.

To identify participants who may not be receiving the full benefits of their inhalers due to inadequate inhalation technique rather than poor PIF, we undertook additional PIF measurements from participants after inviting them to inhale the same way they would at home. We asked users of DPIs with resistance levels ranging from low (R1) to high (R5) to exhale fully and inhale as hard and fast as possible through the inhaler device while gently and slowly inhaling for those on devices, pMDI or SMI, with no resistance (R0).

Based on their PIF values, we then divided the participants into three categories to assess adherence, defined as the ability and willingness to use their inhaler effectively. The first group included those whose typical PIF was equal to or greater than the optimal PIF for their inhaler and identified as 'can and will do'. The second group included participants who were capable of generating sufficient PIF values that matched or exceeded the optimal PIF, but their typical PIF was less than the optimal PIF and they were classified as 'can, but won't do'. The third group comprised participants who were incapable of achieving the optimal PIF, and they were identified as 'cannot do'.

Optimal PIF was defined as typical PIF ≥to what was required for the inhaler devices, while suboptimal PIF was defined as typical PIF <than what was required for the inhalers tested in the study (table 1).[10]

Table 1 Inhaler devices and their optimal PIF and minimal PIF required for effective inhalation among study participants[36 37]

Check-In device resistance	Inhaler devices	Optimal PIF value (L/min)	Minimal PIF required (L/min)
pMDI/SMI (R0)	Respimat (SMI)	60*	20
	Multiple pMDIs	60*	20
Low (R1)	Breezhaler	60	50
	Incruise Ellipta	60	30
Low-medium (R2)	Anoro Ellipta	60	30
	Accuhaler	60	30
Medium (R3)	Symbicort Turbohaler	60	30
	GenuAir	45	40
	Diskus	60	30
	Spiromax	40	40
Medium-high (R4)	NEXThaler	35	35
	Pulmicort Turbohaler	60	30
High (R5)	Easyhaler	30	20
	Handyhaler	30	20

*Note: for pMDI/SMI devices, optimal PIF is considered below 60 L/min, and for DPI devices, optimal PIF is considered above 60 L/min (or based on the specific required PIF for the inhaler device).
DPI, Dry Powder Inhaler; PIF, Peak Inspiratory Flow; pMDI, pressurised Metered-Dose Inhaler; SMI, Soft Mist Inhaler.

Data collection and management

All information collected from participants was handled confidentially and recorded into a clinical data management system (CDMS) using an electronic Case Report Form (eCRF) filled out by the investigator of each study centre on receiving training and individual system access rights.

The used CDMS stored the collected data, which were regularly reviewed for consistency by a data manager (Bioclever in Barcelona, Spain) using automated logical checks or manual review to ensure the correct entering, management and storage of data in the system.

Sample size calculation

To calculate the sample size, we applied the formula developed by Schoenfeld,[16] taking into account the HR for all-cause rehospitalisation observed in patients with suboptimal PIF, which we assumed to be 33% based on relevant literature.[17 18] Considering a dropout rate of 15%, we concluded that recruiting 382 participants would provide 80% power with an α of 0.05.

Patient and public involvement

Participants were not involved in the design of the study or in the development of the research question and outcome measures. However, they were fully informed about the study's purpose and procedures through an information sheet, and written informed consent was obtained prior to participation. Participants were involved in the recruitment process, with clinical staff approaching and enrolling eligible participants. Results were not disseminated to study participants.

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As this study was not a randomised controlled trial, the burden of the intervention was not assessed by participants themselves.

Statistical analysis

The study analysis followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) criteria.

The data analysis was performed using R, an open-source software programme based on the S language, to assess the variables analysed and expressed according to their nature: qualitative variables as frequencies and percentages, and the quantitative variables as means and SD when they fitted a normal distribution curve or were defined as medians and IQRs when required. Initially, all demographics and clinical characteristics were analysed and then evaluated within study groups using χ^2 tests (exact Fisher test with observed frequencies <5) for categorical variables and Mann-Whitney U tests for independent quantitative data. A statistically significant result was defined as p values less than or equal to 0.05.

RESULTS

A total of 17 centres in seven countries participated in the study; they recruited a total of 415 participants. Their demographics and clinical characteristics are shown in table 2. Briefly, 47 participants (11%) were women, with a mean age of 70 (±8.7) years; the mean BMI was 24.5 (±4.8), and 96 (23%) of the participants were people who actively smoke. A high percentage of participants belonged to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) group A/B (n=340, 82%) showing no history of exacerbation, but reporting symptoms of dyspnoea, cough and sputum (mean total CAT score=14.2 (±7.3)). The mean prebronchodilator FEV_1 (predicted) was 48.1 %, FEV1/FVC (predicted) was 43.6% and the actual measured prebronchodilator FVC was 2.32 L.

Within the cohort of 415 participants, it was noted that 280 patients (67%) exhibited optimal PIF values, while 135 participants (33%) demonstrated suboptimal PIF values. Participants with suboptimal PIF values exhibited lower levels of prebronchodilator FEV_1 (predicted)=44.7%, FEV1/FVC (predicted)=38.1% and actual measured prebronchodilator FVC=2.16 L, in contrast to those with optimal PIF values, whose corresponding values were prebronchodilator FEV_1 (predicted)=50.2%, FEV1/FVC (predicted)=45.1% and the actual measured prebronchodilator FVC was 2.34 L. Additionally, participants with suboptimal PIF values showed a higher mean total CAT score (17.7±7) compared with their counterparts with optimal PIF values (12.1±7.6). Table 2 provides a detailed comparative analysis of the demographic and clinical characteristics between participants with optimal PIF and those with suboptimal PIF values.

Among the 415 participants, 76 (18%) used SMIs, while 72 (17%) used pMDIs and the remaining 267 participants (64%) were on DPIs. Of those on DPIs, 50 participants (19%) used DPIs with low internal resistance (R1), 162 participants (61%) were on DPIs at medium-low R (R2), 36 participants (13%) were on medium R (R3) and only a few participants, 8 (3%) and 11 (4%) used DPIs with medium-high (R4) and high R (R5), respectively (figure 1). Further analysis revealed that for each inhaler resistance, there was a proportion of participants with suboptimal PIF values, as shown in table 3. Specifically, the table outlines the distribution of participants across various inhaler devices and resistance levels, highlighting the prevalence of optimal and suboptimal PIF values for each device.

The TAI-12 tests were used to assess medication adherence in the study. It revealed substantial non-compliance among participants, with notable rates of non-adherence observed among those with suboptimal PIF values. Specifically, 51 (33%) participants classified as unconscious non-compliance, 56 (37%) deliberate non-compliance and 28 (26%) erratic non-compliance demonstrated suboptimal PIF values.

The link between suboptimal PIF (as typical PIF <than what was required for the inhalers tested in the study) and adherence was further investigated by categorising participants using their inhaler devices into three groups: 'can and will do', 'can, but won't do' and 'cannot do'. Results showed that while most participants (n=168, 59%) produced an optimal PIF ('can and will do'), a portion of these were either unable to achieve this (n=37, 14%, 'cannot do') or could generate an optimal PIF, but failed to do so (n=73, 27%, 'can, but won't do') (figure 2a). Interestingly, a percentage of participants who generated insufficient values of PIFs was observed at each DPI resistance group from low to high resistance, respectively (figure 2b).

Regarding medication, participants predominantly were treated with LAMA in combination with LABA and/or inhaled corticosteroids. The most common comorbidities found in COPD participants at the baseline visit were cardiovascular diseases, hypertension, asthma and diabetes (online supplemental table 1).

DISCUSSION

COPD remains a significant global health concern due to its high mortality rates and the substantial impact it imposes on affected individuals.[19] Inhaler therapy, representing a cornerstone in managing COPD symptoms,[20] necessitates careful consideration of inhaler device selection due to the diversity in their mechanisms and effectiveness.[21–23] Our study, conducted across 17 multinational centres, sheds light on the prevalence of suboptimal PIF and the implications of inhaler choice in patients with COPD, providing insights into the clinical significance of PIF.

Among the 415 participants, our study revealed that 18% of DPI users (n=75) had suboptimal values of PIF when assessed across various DPI resistance levels (from low (R1) to high (R5)), in contrast to 14% of participants

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Table 2 Patient baseline demographics and clinical characteristics of the participants enrolled in the study (N=415)

	Total no of participants (N=415)	Optimal PIF (n=280)	Suboptimal PIF (n=135)	P value
Demographics				
Age (years), mean (±SD)	70 (8.7)	70.3 (7.6)	69.5 (9.9)	0.66
Sex, n (%)				
Female	47 (11)	28 (10)	19 (14)	0.54
Male	368 (89)	252 (90)	116 (86)	0.54
Height (cm)	166.2 (8.3)	165.6 (8.2)	164 (8)	0.38
Weight (Kg)	67.9 (14.8)	67.6 (14.9)	65 (16)	0.44
BMI (Kg/m2)	24.5 (4.8)	24.6 (4.9)	24.5 (4.7)	0.72
Smoking status, n (%)				
People who currently smoke	96 (23)	53 (18)	43 (25)	0.64
People who quit smoking	319 (77)	227 (82)	92 (75)	0.64
No of cigarettes per day, mean (±SD)	22.9 (15.3)	24.4 (17.2)	21.1 (12.5)	0.006
Smoking pack years, mean (±SD)	43.8 (33.1)	48.9 (38.9)	37.7 (22.9)	0.8
Clinical characteristics				
Pulmonary function tests				
Prebronchodilator values:				
FVC (L)	2.32 (1549.3)	2.34 (1578)	2.16 (1404.5)	<0.001
FEV1 (L/s)	1.22 (893.3)	1.36 (910.6)	1.15 (804.9)	<0.001
FEV1 (%)	48.1 (28.4)	50.2 (28.4)	44.7 (27.6)	0.006
FEV1/FVC (%)	43.6 (23.1)	45.1 (22.5)	38.1 (26)	0.005
Postbronchodilator values:				
FVC (L)	2.64 (1261.5)	2.79 (1217.9)	2.51 (1081.8)	<0.001
FEV1 (L/s)	1.49 (776.9)	1.52 (744.2)	1.44 (814.2)	<0.001
FEV1 (%)	56.2 (21.4)	58.8 (21.4)	52.2 (23.1)	0.006
FEV1/FVC (%)	51 (15.2)	52.8 (14.6)	48 (18.1)	0.011
Inspiratory capacity (L)	1.191 (1054.8)	1.290 (1028.6)	1.073 (1076.3)	<0.001
GOLD 2019 category, n (%)				
Total CAT score, mean (±SD)	14.2 (7.3)	12.1 (7.6)	17.7 (7.0)	0.007
GOLD A	133 (32)	67 (24)	66 (49)	0.32
GOLD B	207 (50)	118 (42)	89 (66)	0.06
GOLD C	21 (5)	9 (4)	12 (9)	0.03
GOLD D	54 (13)	33 (12)	21 (16)	
Blood biomarkers, mean (±SD) (n=257)				
Eosinophil count (x10^9/L)	0.147 (0.35)	0.157 (0.27)	0.138 (0.18)	0.001
Platelets count (x10^9/L)	191.7 (110.6)	197.6 (114)	184.6 (106.2)	0.01
Haemoglobin (g/L)	118 (56)	119 (56)	113 (56)	
Leucocytes count (x10^9/L)	38.7 (535.3)	54.2 (667.4)	25.7 (485.1)	0.002
COPD phenotype, n (%)				
Chronic bronchitis	104 (25)	61 (22)	43 (32)	0.001
Asthma overlap COPD	52 (13)	40 (14)	12 (9)	
Emphysema	216 (52)	160 (57)	56 (41)	
Exacerbator	44 (10)	20 (7)	24 (18)	0.01
Exacerbations, n (%)				
Moderate (acute courses of antibiotics or oral steroids for COPD):				
0	344 (83)	236 (84)	108 (80)	0.089

Continued

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Table 2 Continued

	Total no of participants (N=415)	Optimal PIF (n=280)	Suboptimal PIF (n=135)	P value
1	36 (9)	26 (9)	10 (7)	
2	18 (4)	5 (2)	13 (10)	
3+	17 (4)	13 (5)	4 (3)	
Severe (emergency room attendance or hospitalisation for >24 hours for COPD):				
0	366 (88)	250 (88)	116 (86)	0.049
1	36 (9)	24 (9)	14 (10)	
2	8 (2)	5 (2)	3 (2)	
3+	5 (1)	3 (1)	2 (2)	

Values are expressed as the mean±SD or absolute (relative) frequencies according to the nature of the variable. P value (≤0.05) calculated using χ^2 tests (exact Fisher test with observed frequencies <5) for categorical variables and Mann Whitney U for continuous variables as well as Student's t-tests when required. Numbers in parentheses are SD, unless otherwise specified.
BMI, Body Mass Index; CAT, COPD Assessment Test; COPD, Chronic Obstructive Disease; FEV1, Forced Expiratory Volume in 1 second; FVC, Forced Vital Capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease; PIF, Peak Inspiratory Flow.

(n=60) using devices with no resistance (R0). This finding underscores the need for careful consideration of inhaler choice, as the specific characteristics of inhalers may significantly influence the prevalence of suboptimal PIF values observed in our cohort. Additionally, 14% of DPI users either failed to achieve an optimal PIF or were unwilling to exert the necessary effort (27%), highlighting potential challenges in medication delivery efficacy. Notably, participants with suboptimal PIF values presented with a higher mean CAT score (17.7±7), indicating a greater burden of COPD symptoms compared with those with optimal PIF values (12.1±7.6). This observation aligns with previous studies linking inhaler technique errors, particularly those related to inspiratory effort in DPI users, to adverse disease outcomes.[24 25] Globally, 37% in not almost half of the participants did not adhere to their treatment, underscoring the urgent need for enhanced patient education and support.

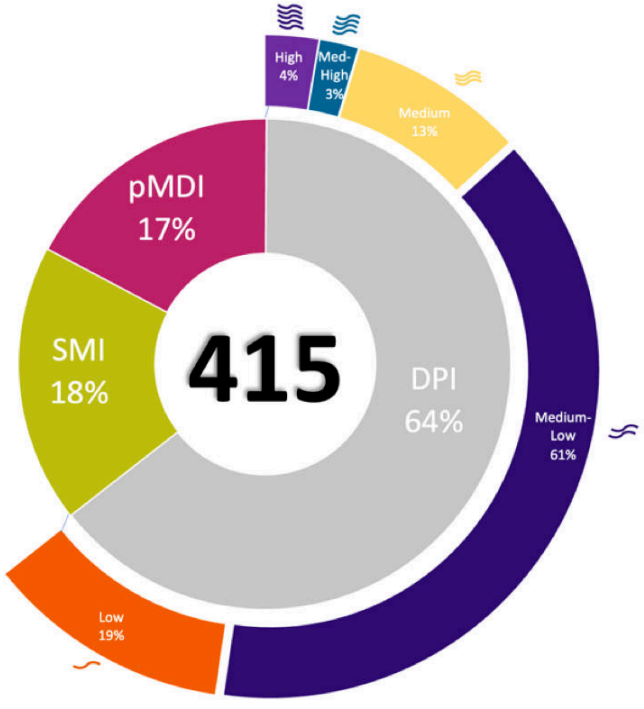

Figure 1 Percentage of pMDIs, SMIs and DPIs used by the 415 participants enrolled in the study and percentage of those on DPIs based on the internal resistance of their inhaler device. DPI, dry powder inhaler; pMDI, pressurised metered-dose inhaler; SMI, soft mist inhaler.

The correlation between suboptimal PIF and adherence illuminates the intricate interplay between inhalation proficiency and patients' ability or willingness to follow prescribed techniques. The representation of women at only 11% may limit the generalisability of our findings. Women with COPD often present differently, may have distinct comorbidities and could respond differently to treatments compared with male patients. Consequently, the prevalence of suboptimal PIF and inadequate inhaler choice observed in this study may not fully reflect the experiences of women with COPD. This low recruitment may be due to factors such as site demographics, historical under-representation of women in COPD trials or sociocultural factors affecting participation. While this imbalance may be coincidental, it is important to consider its potential impact, and future research should aim for a more balanced gender representation to better address these issues.

The observed differences in lung function parameters, including FEV1 and FVC, between participants with optimal and suboptimal PIF values reinforce the prevalence of suboptimal inhalation techniques among patients with COPD. This finding underscores the necessity for targeted interventions aimed at optimising PIF to improve inhaler efficacy and patient outcomes.[26] Participants with suboptimal PIF values exhibited lower FEV_1 and FVC compared with those with optimal PIF values, suggesting a potential link between suboptimal inhalation

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Table 3 Proportion of participants with optimal and suboptimal PIF for each inhaler device across different resistance levels (R0–R5)

Check-In device resistance	Inhaler devices	Tot of participants/device (N=415)	Tot of participants with optimal PIF (n=280)	Tot of participants with suboptimal PIF (n=135)
pMDI/SMI (R0)	Respimat (SMI)	76 (51.3)	55 (62.5)	21 (35)
	Multiple pMDIs	72 (48.7)	33 (37.5)	39 (65)
Total, n		*148*	*88*	*60*
Low (R1)	Breezhaler	34 (68)	27 (69.2)	7 (63.6)
	Incruise Ellipta	16 (32)	12 (30.8)	4 (36.4)
Total, n		*50*	*39*	*11*
Low-medium (R2)	Anoro Ellipta	128 (79)	95 (82.6)	33 (70.2)
	Accuhaler	34 (21)	20 (17.4)	14 (29.8)
Total, n		*162*	*115*	*47*
Medium (R3)	Symbicort Turbohaler	23 (63.9)	15 (60)	8 (72.7)
	GenuAir	10 (27.8)	7 (28)	3 (27.3)
	Diskus	2 (5.5)	2 (8)	0
	Spiromax	1 (2.8)	1 (4)	0
Total, n		*36*	*25*	*11*
Medium-high (R4)	NEXThaler	3 (37.5)	3 (50)	0
	Pulmicort Turbohaler	5 (62.5)	3 (50)	2 (100)
Total, n		*8*	*6*	*2*
High (R5)	Easyhaler	2 (18.2)	1 (14.3)	1 (25)
	Handyhaler	9 (81.8)	6 (85.7)	3 (75)
Total, n		*11*	*7*	*4*

Note: the numbers in parentheses represent the percentage for each device relative to the total number of participants in each device resistance group.
PIF, Peak Inspiratory Flow; pMDI, pressurised Metered-Dose Inhaler; SMI, Soft Mist Inhaler.

efforts and compromised lung function, reinforcing the importance of adequate inspiratory flow for optimal drug delivery in COPD management.[27] This finding aligns with existing research, which has consistently linked suboptimal inhalation techniques, as reflected by PIF values, to adverse outcomes in COPD management.[28] Specifically, compromised lung function in patients with suboptimal PIF values suggests that the ability to generate an adequate inspiratory flow may directly impact the effective delivery of therapeutic agents. Therefore, interventions and strategies aimed at optimising PIF, such as personalised inhaler selection and patient education, may play a pivotal role in enhancing the clinical outcomes of patients with COPD. These insights underscore the nexus of inhalation proficiency, lung function and therapeutic effectiveness, emphasising the need for a holistic approach in managing respiratory conditions.[29 30]

The analysis of inhaler device usage reveals a substantial proportion of participants using DPIs with varying internal resistance. Notably, participants using DPIs with higher resistances exhibited a higher prevalence of suboptimal PIF values. This emphasises the need for a personalised approach in selecting inhaler devices tailored to individual patients' characteristics to optimise drug delivery.[31] The observed variations in suboptimal PIF across distinct DPI resistance levels underscore the influential role of device-specific characteristics in inhalation efficacy.[32] Patients using DPIs with lower resistance levels (R0 and R1) displayed a higher incidence of suboptimal PIF, potentially linked to the ease of generating excessive airflow. Conversely, DPIs with medium and higher resistance levels (R3, R4, R5) exhibited a reduced occurrence of suboptimal PIF, suggesting a demand for a more controlled and forceful inhalation technique with these resistances.[33]

This information underscores the imperative of tailoring inhaler selection to individual patient characteristics, incorporating considerations such as inspiratory capacity and resistance levels. This personalised approach aims to optimise therapeutic outcomes in respiratory condition management.[34 35] Additionally, it emphasises the responsibility of healthcare professionals in thoroughly assessing and guiding patients to select the most suitable DPI based on their distinctive needs and abilities.

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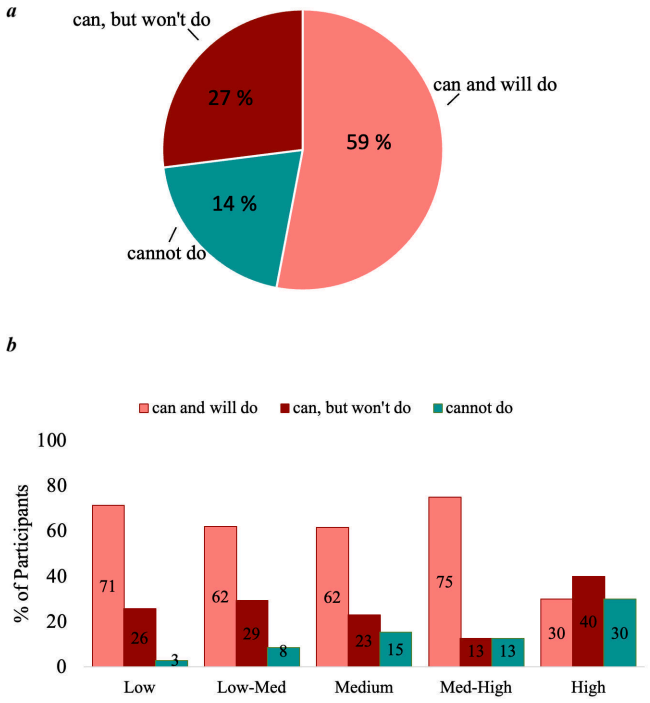

Figure 2 Percentage of participants (N=267) (a) who 'can and will do', 'can, but won't do' and 'cannot do' an optimal PIF. (b) Analysis of the three categories based on in-Check DIAL G16 device by the five internal resistance groups. PIF, peak inspiratory flow.

Shifting focus to medication adherence, evaluated through the TAI-12 tests, our study reveals a concerning reality where 37% of participants exhibit poor adherence to their prescribed medication regimen. The correlation between suboptimal PIF and adherence illuminates the intricate interplay between inhalation proficiency and patients' commitment or capability to adhere to prescribed techniques.

The findings from our study highlight the importance of choosing the right inhaler device for each patient to improve the outcomes of respiratory care. This patient-centred approach, encompassing personalised inhaler choices and adherence strategies, is crucial for improving the quality of care in COPD management.

In conclusion, our multicentre study highlights the significance of PIF assessment in COPD management. Evaluating PIF values proves crucial in determining a patient's ability to achieve optimal inhalation for the selected device, guiding inspiratory efforts effectively. This assessment, covering different resistance levels of DPI, is essential to determine whether a patient can effectively use a DPI or requires an alternative inhaler, such as a pMDI or an SMI, while considering patients' preferences and lifestyle.

We advocate for the routine assessment of PIF in every patient with COPD before prescribing an inhaler, ensuring optimal device selection and preventing complications. This approach should be an ongoing practice to maintain disease control effectively.

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Contributors OU, guarantor of this manuscript, contributed to the conception and design of the study, as well as the supervision and review and editing of the manuscript. VP was responsible for project management, formal analysis, and led the preparation of the manuscript from initial draft through to final editing prior

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