Short Report

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Viability of a new home program of forced spirometry with bronchodilator response measurement in the assessment of patients with asthma

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ABSTRACT

Background: Home spirometry using portable devices offers a potential alternative for asthma management by reducing hospital dependence and improving accessibility. This study aimed to assess the feasibility of a home spirometry program with bronchodilator response (BDR) testing performed without direct medical supervision.
Methods: A prospective observational study was conducted with 47 asthma patients from a tertiary hospital. Participants received clear instructions and performed forced spirometry with BDR testing at home using a portable device. The primary outcomes included spirometry quality, variability compared to hospital tests, and patient satisfaction.
Results: A total of 78% of participants achieved high-quality spirometry (A or B, according to ATS/ERS criteria), despite greater variability in forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1) compared to hospital tests. However, the results remained clinically acceptable. Patients reported high satisfaction with the device, highlighting its ease of use and convenience.
Conclusions: Home spirometry with BDR testing is a feasible tool for asthma follow-up, maintaining acceptable quality while reducing hospital-based testing. Although improvements are needed to minimize variability and enhance consistency, this program has the potential to optimize asthma management, increase accessibility, and reduce the burden on healthcare facilities.

Key words: home spirometry, asthma, bronchodilator response, pulmonary function, telemedicine

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Authors' contributions: H.C.C. and M.M.E. conceptualized the study, coordinated the research activities, and supervised the entire project. A.M.R.O. processed the spirometry tests and ensured the accuracy of the data collected. C.B.A. and S.S. participated in patient recruitment and data collection. S.A.G. and J.B.M. performed statistical analyses and contributed to the interpretation of the results. N.F. and E.M.G.C. provided methodological support and assisted in drafting and editing the manuscript. G.S.C. provided technical guidance and oversight of the research design. M.M.E. prepared Figure 1, Tables 1-2 and managed the submission process. All authors reviewed and approved the final version of the manuscript.

Ethics approval and consent to participate: This study was conducted as an observational, non-interventional study during the COVID-19 pandemic, in which standard hospital-based pulmonary function tests were not feasible. Since no interventions, modifications to treatment, or experimental procedures were performed, formal approval from an ethics committee was not required according to institutional regulations. All participants voluntarily agreed to perform home spirometry as an alternative to hospital-based testing. They were informed about the study objectives and procedures, and they provided written informed consent for the processing of their personal and health data in compliance with data protection regulations. No personally identifiable information was shared or disclosed. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and adhered to standard guidelines for patient confidentiality and data protection.

Consent for publication: The authors hereby give their consent for the publication of this manuscript in the journal. We confirm that all authors have reviewed and approved the final version of the manuscript, and we agree to its submission and potential publication. Furthermore, if the study includes identifiable patient data, we confirm that appropriate consent has been obtained from the participants.

Availability of data and material: The datasets generated and analyzed during this study are not publicly available due to privacy and ethical restrictions. However, anonymized data, with all personally identifiable information removed, may be made available upon reasonable request from the corresponding author. Requests will be evaluated in accordance with institutional and ethical guidelines to ensure compliance with data protection regulations.

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Introduction

Asthma is a chronic illness of the respiratory airways characterized by variable airflow obstruction and bronchial hyper-responsiveness [1,2]. Forced spirometry with bronchodilation response (BDR) test is used to assess pulmonary function in asthma patients, allowing measurement of obstruction severity and its reversibility. These two prognostic factors are essential in determining treatment levels and preventing exacerbations [3,4]. In clinical practice, testing is performed in healthcare facilities under specialized supervision to ensure the best quality results. The process takes over 40 minutes in total, including 15-20 minutes of waiting time to evaluate the BDR test [5]. However, dependence on clinical settings can overburden healthcare systems, especially with increasing chronicity. This is compounded by the heightened risk of respiratory virus transmission, as seen with SARS-COV2 in 2020 [6].

Until now, peak flow measurements have been used to assess pulmonary function at home; however, it presents important drawbacks in precision and variability. This method also lacks quality criteria [7,8]. Home spirometry emerges as a promising alternative for managing chronic respiratory illnesses such as asthma [3]. Previous studies show home spirometry with portable devices offers reliable results, improving access to pulmonary function tests [9,10].

This study aimed to evaluate the viability and quality of home spirometry with BDR for asthma patients using portable devices without direct medical supervision.

Methods

Study design and scope

This was a prospective observational study in which subject enrollment began against the backdrop of the SARS-COV2 pandemic in November 2020. The subjects included were adult patients from the asthma clinic at Bellvitge University Hospital (Barcelona, Spain)

with a definitive diagnosis of asthma in a stable state. Among the inclusion criteria was a prior spirometry in the center of A or B quality, according to the ATS/ERS criteria [6]. Participants were also required to be able to use the electronic devices that were provided for their participation in the study. As to the exclusion criteria, it was decided not to include patients who had previously participated in an asthma clinical trial that included the use of a device to measure pulmonary function at home.

Variables

Demographic and clinical data were collected, including age, sex, weight, smoking history, age of asthma onset, asthma treatment, therapeutic grading based on the Global Initiative for Asthma (GINA) [3], the degree of asthma symptom control (measured with the Asthma Control Test (ACT)), the number of exacerbations in the previous year, and variables of lung function tests.

Procedures and data collection

A Spirodoc (MIR, Italy) portable spirometer was provided on loan to each patient. This device allowed them measure all the spirometric parameters (FVC, FEV_1, FEV_1/FVC%, PEF, FEF25%, FEF50%, FEF75%, FEF25-75%) and BDR test (in the same way as is done in the hospital.

All participants received written instructions with illustrations concerning the use and maintenance of the device. They were asked to carry out forced spirometry with BDR at home (without healthcare professional assistance) and return the spirometer for data analysis. Patients also completed a survey assessing satisfaction with the program and provided suggestions for improvement.

The main assessment variable was the quality and variability of forced spirometry per ATS/ERS criteria (2019) [6], with A quality defined as three acceptable spirometries with variability ≤ 150 ml, while B allowed up to 200 ml. Categories C and D permitted greater variability or fewer acceptable maneuvers, and E and F indicated inadequate or uninterpretable tests. In addition, we compared the variability between hospital and home spirometry maneuvers.

The time spent by the staff providing instructions to patients on the use of the device and the time required for reviewing the test results was recorded. Patient satisfaction and ease of use of the device were assessed using a visual analog scale (VAS) ranging from 0 to 10, where 0 represents "very dissatisfied" and 10 represents "completely satisfied".

Data analysis

The qualitative variables were expressed as frequencies and percentages and the continuous variables as the mean and standard deviation in the case of normal distribution, and as the median and the interquartile range in the case of non-parametric distribution. For the comparison of the quality between home versus hospital spirometries, non-parametric Mann-Whitney U test was used. Statistical significance was set at 5% (α=0.05). For statistical analysis we used the SPSS software package (version 21.0, Inc., Chicago, Il, USA).

A repeated-measures ANOVA was performed to compare spirometry measurements obtained in hospital-based and home-based settings. Since only two time points were included, the assumption of sphericity was not applicable and was therefore considered met by default (W = 1.000). Statistical significance was set at 5% (α = 0.05). All analyses were conducted using the SPSS software package (version 21.0; IBM Corp., Armonk, NY, USA).

Results

Forty-seven patients were included in the study, out of whom 68.1% (n=32) were women. A total of 74.4% (n=35) of the patients were classified as having severe asthma, with a score of 4 or higher on the GINA therapeutic scale, and they showed well-controlled symptoms, with an ACT score of 21 points and without exacerbations in the year prior to inclusion in the protocol. The sociodemographic and clinical data of the patients are presented in Table 1.

All patients in the study correctly performed home spirometry with BDR test using the provided device. The number of valid maneuvers was three, both

Table 1. Sociodemographic and clinical data (n=47)

Variables	N = 47
Age, years	52 [45-63]
Female gender, n (%)	32 (68,1%)
Weight, Kg.	71 [63-82]
Body mass index, Kg/m^2	27.11 [23.49-30.22]
Smoking status	
Never smoker	27 (57.4%)
Past-smoker	18 (38.3%)
Current smoker	2 (4.3%)
Age at asthma onset, years	38 [20-47]
Number of exacerbations in the previous year	0 [0]
ACT score, points	21 [15-24]
GINA scale, n (%)	
1 - Use of Salbutamol or ICS/formoterol as required	4 (8.5%)
2 - Use of low dose of ICS	3 (6.4 %)
3 - Use of low dose of ICS/LABA	5 (10.7 %)
4 - Use of medium dose ICS/LABA	8 (17 %)
5 - Use of high dose of ICS/LABA	27 (57.4 %)
Use of biological treatment, n (%)	18 (38.3%)
Mepolizumab	7 (14.9 %)
Omalizumab	7 (14.9 %)
Benralizumab	2 (4.3%)
Dupilumab	1 (2.1%)
Reslizumab	1 (2.1%)
Use of maintenance steroids *(Oral corticosteroids)*, n%	5 (10.6%)
Use of LAMA, n (%)	9 (19.1%)
Use of theophylline, n (%)	3 (6.4%)
Use of cyclic azithromycin, n (%)	1 (2.1%)
Use of antileukotrienes, n (%)	15 (31.9%)

Data are displayed as median [interquartile range]. ACT (Asthma Control Test); GINA, Global Initiative for Asthma; ICS, Inhaled Corticosteroids; LABA, Long-Acting Beta-Agonists; LAMA, Long-Acting Muscarinic Antagonists.

for baseline spirometry and after bronchodilator administration. As shown in Figure 1, the quality level of home spirometry was graded A or B in 78% of cases (n = 36).

In addition to the home-based test, all patients underwent hospital-based spirometry. The median

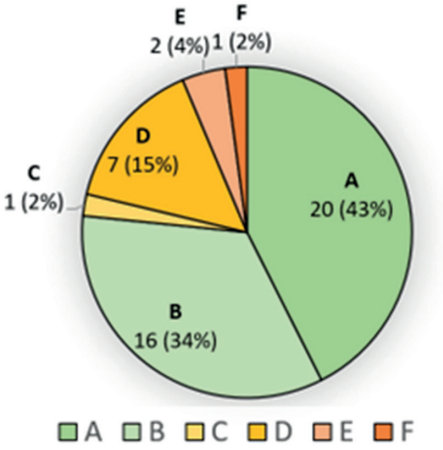

Figure 1. Distribution of home spirometry quality grades according to the 2019 ATS/ERS criteria, n(%).

time interval between the two tests was 13.3 months (interquartile range: 5.6–20 months). It is noteworthy that the home-based measurements were conducted during the COVID-19 pandemic, when spirometry was considered a high-risk procedure for viral transmission; this context explains the prolonged interval between tests in some patients.

The analysis revealed no statistically significant differences between hospital and home-based spirometry in terms of FVC, FEV_1, or reversibility test values, whether expressed in Liters or as percentages of predicted values (Table 2). The within-test variability observed in home-based spirometry was 100 mL (2.7%) for FVC and 65 mL (2.8%) for FEV_1. By contrast, the within-test variability in hospital-based spirometry was 40 mL (1.5%) for FVC and 30 mL (1.5%) for FEV_1. Furthermore, the between-test variability—comparing home versus hospital spirometry—was 60 mL for FVC and 35 mL for FEV_1, both favouring the hospital setting ($p = 0.025$ and $p = 0.015$, respectively).

The time spent by professional nurses in providing explanations and downloading data was a total of 15 minutes in both cases, and the time it took for patients to carry out home spirometries was thirty minutes on average. About 53% of the tests were carried out between 8 a.m. and 12 a.m.

On the questionnaires concerning patient satisfaction and quality following the use of the devices at home, 36 patients (76.59%) responded, and they

Table 2. Results of home spirometry versus hospital spirometry (n=47)

	Home Spirometry		Hospital Spirometry		
Variable	**PRE-BD**	**POST-BD**	**PRE-BD**	**POST-BD**	**P value***
FVC (L)	3.12 [2.51-4.12]	3.21 [2.53-4.30]	3.27 [2.69-4.01]	3.08 [2.75-4.07]	0.145
FVC (%)	103 [90-115]	107 [92-116]	108 [95-118]	105 [96-123]	0.051
FEV_1 (L)	2.19 [1.73-2.8]	2.43 [1.72-2.91]	2.27 [1.71-2.87]	2.40 [1.70-3.02]	0.091
FEV_1 (%)	83 [69-101]	90 [76-105]	86 [68-104]	94 [74.5-109.5]	0.139
Reversibility Test (change in FEV_1%)	6 [2-17]		5 [1.5-12]		0.291
Number of maneuvers	3 [3-3]	3 [3-3]	3 [3-4]	3 [3-3]	0.037
Number of valid maneuvers	3 [2-3]	3 [3-3]	3 [3-3]	2 [2-2]	0.001
Within-test variability in FVC (mL)	100ml [40-140]		40ml [20 -80]		0.025
Within-test variability in FVC (%)	2.7% [1.3-5.5]		1.5% [0.6-2.5]		0.012
Within-test variability in FEV_1 (mL)	65ml (30-115)		30ml [10-50]		0.015
Within-test variability in FEV_1 (%)	2.8% [1.3-6.2]		1.5% [0.5-2.6]		0.008

Data are presented as median [interquartile range]. BD, bronchodilation; FVC, forced vital capacity; FEV_1, forced expiratory volume in 1 second. P value reflects between-test variability (comparison between hospital-based and home-based settings in pre-BD manoeuvres), assessed using repeated-measures ANOVA.

showed a level of satisfaction of 9 out of 10, and on the ease of use of the device the score was 8 out of 10.

Discussion

The establishment of new out-of-hospital programs where home spirometry can be performed while maintaining quality standards could improve asthma management. Our results show that around 80% of patients achieved good-quality spirometry at home. While home spirometry exhibited greater variability than hospital-based tests, this variability was not clinically significant. These findings align with prior studies [6,11,12].

Few studies have explored home spirometry in asthma, particularly for adults without supervision, making this study innovative. Besides improving access to testing, this approach could reduce waiting lists and enable earlier diagnosis, which is critical for optimizing asthma management. Early detection enhances disease control, reduces costs linked to complications, and significantly improves patients' quality of life. As seen with Home Polysomnography or Holter monitoring, extra-hospital circuits have proven viable. This article opens the door to extending this approach to spirometry for reliable home-based assessments for the control and follow-up of the asthmatic patient [3,13,14,15].

Comparative studies support the reliability of home spirometry in chronic illnesses. Research on idiopathic pulmonary fibrosis showed week-to-week variability of less than 8.2% in home spirometry readings [16,17]. These findings strengthen the case for using home spirometry even for complex conditions. However, managing specific populations, such as paediatric patients, poses additional challenges. For instance, Gerzon et al. found that children face greater difficulties performing tests without supervision, emphasizing the importance of tailoring these programs to patients' age and unique needs [10].

One of the most important contributions made by the present study is the inclusion of BDR test in

the home setting. This is the first study to report the viability of carrying out this test without direct medical supervision [10,18]. Detecting a positive BDR is critical, as it is a key prognostic factor in asthma management because persistent reversibility in patients undergoing therapy may be a factor associated with an increased risk of exacerbation [3]. Integrating BDR test into out-of-hospital testing allows for greater personalization of treatment and enhances the precision of follow-up care. While promising, the absence of prior research highlights the need for further studies to assess its broader impact and scalability.

Another relevant aspect was the patient experience. Participants rated the portable spirometer highly, with an average score of 8/10 for ease of use and 9/10 for overall satisfaction. This positive feedback reinforces the idea that simple and accessible designs improve adherence to home-based health technologies. These results align with other studies reporting high satisfaction levels with home spirometry programs [9,11,18]. Patients appreciated the convenience of performing tests at home, which reduces the need for frequent hospital visits and streamlines disease management.

Regarding the limitations of our study, one notable constraint is the relatively small sample size, which restricts the generalizability of findings to the larger population. To address this, we applied clear and rigorous criteria to ensure the data represented regular care patients as accurately as possible. Additionally, this is the first study to assess BDR test without direct professional supervision in a home setting, limiting comparisons with other centers and the full evaluation of its practical viability. Despite these limitations, our study serves as a foundational step in establishing guidelines for future research.

Conclusions

This study demonstrates that home spirometry with bronchodilator response testing is a viable and effective tool for asthma management. A significant proportion of patients were able to perform high-quality spirometry at home, with clinically acceptable variability. Additionally, patients reported high satisfaction and ease of use. While some variability was observed compared to hospital-based spirometry, the overall feasibility and reliability of the home testing approach support its implementation in clinical practice. Further research is needed to optimize its use and expand its applicability in broader patient populations.

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Supplementary Materials

Instructions for Using a Home Spirometer

SPIROMETER USE

1

Remove the wrapper and insert the turbine (plastic/black side first) into its housing until it stops, then rotate clockwise.

SPIROMETER USE

2

Turn on the device using the ON button.

A menu will appear—press the SPIRO button on the screen.

Then select FVC, and the device will be ready to perform spirometry."

SPIROMETER USE

3

1. Place the nose clips on the nose to prevent air from escaping.

2. Hold the spirometer and grip it like a mobile phone. The screen should always face the patient.

3. Place the mouthpiece (white cardboard area) in your mouth, making sure no air escapes from the sides.

SPIROMETER USE

4

4. Before starting the test, breathe normally for a few moments. When ready, inhale slowly as much air as possible, then blow out hard as fast as you can without stopping (you'll hear an intermittent beep indicating you should continue, until you hear a continuous beep indicating you should take a deep breath to maximum capacity).

5. When finished, wait for the results to appear, then press the back arrow and repeat the FVC maneuver at least 2 more times.

6. Remove the nose clips.

SPIROMETER USE

5

BRONCHODILATOR TEST

1. Administer 4 puffs of salbutamol (using the spacer), then wait **15-20 minutes** (at rest).

2. On the home screen, press **POST**, then **OK**, and select **FVC** again.

3. Place the nose clips.

4. Repeat steps 3 and 4 (complete **3 FVC maneuvers**).

SPIROMETER USE

6

1. To finish, press the ON/OFF button on the top.

2. Remove the entire mouthpiece by turning it counterclockwise.

3. Discard the mouthpiece and nose clips in the trash.

4. Store the spirometer in its case.