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DIAGNOSTICS

Home self-monitoring in patients with asthma using a mobile spirometry system

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ABSTRACT

Background: Self-management is an appealing strategy for prevention of asthma exacerbations. This study aimed to evaluate the feasibility and safety of a portable spirometer for unsupervised home spirometry measurements among patients with asthma.

Methods: A multi-center, prospective, single-arm, open study recruited 86 patients with controlled or partly controlled asthma (41 women, 38.6 ± 10.4 y/o and 45 men, 36.2 ± 12.1 y/o). After a training session, patients performed daily spirometry at home with the AioCare® mobile spirometry system. Each spirometry examination was recorded and evaluated according to the ATS/ERS acceptability and repeatability criteria. The primary endpoint was defined as three or more acceptable examinations in any given seven-day period (+/- 1 day) during any of the three weeks of the study. The system allowed for online review of measurements by physicians/nurses to provide feedback to patients.

Results: Of 78 patients with complete data, 67 (86%) achieved the primary endpoint. Seventy-five (96%) participants used the device correctly once or more, and 10 (13%) patients succeeded every single day over the three-week follow-up. The rate of acceptable spirometry examinations differed between the sites ($p = 0.013$). Retraining was required in 20 of 62 (32%) eligible patients, and successful in 8 individuals (40%). Satisfaction with the AioCare® system was high, 90% of respondents perceived it as useful and user-friendly.

Conclusions: Self-monitoring of asthma with a connected mobile spirometer is feasible, safe and satisfactory for patients with asthma. It remains to be established whether unsupervised home spirometry measurements may improve early diagnosis and outcomes of self-management in cases of exacerbation or loss of asthma control.

HIGHLIGHTS BOX

This study aimed to evaluate the ability of patients with asthma to perform high-quality daily spirometry examinations at home with using the AioCare® mobile spirometry system. The study showed that unsupervised home spirometry is safe and feasible in patients with asthma. Most patients used the device on most days of the study, and nearly 90% of all patients achieved the primary endpoint. There were no device-related adverse events.

Abbreviations: FEV1: forced expiratory volume in one second; FVC: vital capacity; PEF: peak expiratory flow

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Introduction

Poor asthma control is the most important reason for asthma-related premature deaths (1–3). Of note, up to half of patients who die due to an exacerbation of asthma do not receive medical assistance in their fatal attack, which could be partly because medical staff fail to identify impending asthma exacerbations (4,5).

Reversible airway obstruction is the key feature of asthma and current practice guidelines recommend spirometry for the diagnosis and management of asthma (6). Moreover, spirometry measurements can be used to predict the risk of asthma exacerbation (7). However, in-office spirometry is not always available and is not convenient for patients, who need to reserve extra time and often travel substantial distances to attend a clinic.

Symptom-guided self-management introduced by patients at early stages of loss of asthma control reduces the risk of severe exacerbation significantly (8). An objective lung function test, in addition to symptoms, may further improve outcomes in these patients. Thus, increasing the availability of spirometry with devices that enable home spirometry is a key task for improving asthma control and reducing the risk of asthma-related hospital admissions and deaths. This study investigated the safety and efficacy of a portable spirometer (AioCare®, HealthUp, Poland) for unsupervised home spirometry measurements among patients with asthma.

Methods

Trial design

This was a multicenter, single-arm, open cohort study assessing the feasibility and safety of a portable spirometry system (AioCare®) in patients with asthma. The study was carried out in six outpatient sites in Poland. The study design and protocol were approved by the local Ethics Committees. All participants signed an informed consent form prior to enrollment.

Inclusion and exclusion criteria

All patients were recruited from the outpatient clinics. Asthma severity and control was defined in line with the GINA 2017 guidelines (6) based on symptoms, rescue medication use, Asthma Control Test (ACT) and medication level needed to maintain asthma control. The inclusion and exclusion criteria are presented in Table 1.

Device description

The AioCare® device is a portable spirometer coupled with a dedicated smartphone application, which analyzes spirometry data acquired from the AioCare® system. The spirometer communicates wirelessly via Bluetooth to the mobile application running on iOS and Android operating systems. The device measures all of the widely used spirometry parameters including forced vital capacity (FVC), forced expiratory volume in one second (FEV1) and peak expiratory flow (PEF). Validation of the AioCare® detector were performed *in vitro* in a pilot study with the application of the Series 1120 Flow/Volume Simulator (Hans-Rudolph Inc Kansas, USA). Data are stored in the smartphone application and accessed via a web-based platform. A photograph of the device is shown in (Figure S1 Supplementary material).

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	cExclusion criteria
• Age ≥ 18 years • Ability to perform spirometry • Diagnosed and treated asthma • Controlled or partly controlled asthma according to the criteria of the Global Initiative for Asthma (2017) • Smartphone ownership (iOS or Android with BT4.0)	• Untreated or uncontrolled asthma • Lung diseases other than asthma, including chronic obstructive pulmonary disease • Aneurysms of the aorta or cerebral arteries • Surgery in the anterior eye segment (e.g. cataract, glaucoma) within 6 months; surgery in the vitreous body (e.g. for retinal detachment) within 2 months; opthalmoplastic surgery within 2 weeks • Increased intracranial pressure • Previous retinal detachment • Hemoptysis without a known cause • Pneumothorax • Myocardial infarction within 6 weeks • Stroke within 6 weeks • Previous ear, nose, or throat surgery • Nausea, vomiting, persistent cough, acute infection • Abdominal or thoracic pain hindering full inspiration and expiration • Vertigo • Cardiac arrhythmia • Pregnancy or lactation • Active participation in another clinical trial

Intervention

At enrollment, each investigator instructed their patients on the correct use of the AioCare® system. Each participant was then asked to perform three correct spirometry measurements once daily, at home, for 21 consecutive days. A window of ± 2 days between consecutive visits was allowed due to logistic issues. Every time a measurement was performed, it was classified by an algorithm built in the AioCare® software as either correct (green dot) or incorrect (red dot) based on American Thoracic Society and European Respiratory Society (ATS/ERS) criteria, which ensured good quality and repeatable measurements. When evaluating the correctness of measurements, attention was paid to: the flow-volume and volume-time curves: • without artifacts during the first second • maximum, uniform exhalation effort • flat end expiration (flat flow curve – volume); the correct beginning of the exhalation: • backwardly extrapolated volume less than 5% of the obtained FVC or 100 ml • time to reach PEF (Time to PEF – tPEF does not exceed 0.3 s); proper end of exhalation: • duration of forced expiration – (FET) not shorter than 6 s, • on the volume/time curve a plateau is observed (practically no change in volume) • in the absence of FET plateau, exhalation not shorter than 15 s. Criteria for the repeatability of the spirometry test included: measurement of the flow – volume curve should be performed correctly at least 3 times. They were defined as reproducible if the two highest FVC values did not differ from each other by more than 150 ml and also the two highest FEV1 values do not differ by more than 150 ml. The measurement result is the maximum values of FEV1 and FVC, which did not have to be obtained in the same tests (9). If the first measurement on a given day was incorrect, the participant was allowed to perform it again. Up to eight attempts were allowed in one day. The spirometry examination was labeled as 'correct' if there were at least 3 correct maneuvers performed and the repeatability criterion was met. The outcome of the last correct measurement was then used for analysis in the study. Two to three days after the first visit, the investigator checked whether participants had used the device correctly, via an online platform. If the number of incorrect measurements was the same or greater than the number of acceptable measurements, participants were retrained on the correct use of the AioCare® System during an extra visit. Participants were asked to input their observations and symptoms after the lung function measurement in a diary (short questionnaire), which was part of the smartphone application. All data including lung function measurements and symptoms were transferred to the database on a daily manner via the wi-fi connection.

Trial endpoints

The primary endpoint was the number and percentage of patients who used the device correctly three times or more within seven days (±1 day) in any of the three weeks of the study. We analyzed patient adherence to the study requirements and the number and percentage of patients who required retraining. Moreover, we studied how often the device was used, both correctly and incorrectly, in different study sites and at different points in time. At enrollment and at study completion, participants evaluated satisfaction and the functionality of the device using a five-point Likert scale. At baseline, patient clinical data were evaluated. Adverse events were recorded throughout the study.

Statistical analysis

The primary end-point was defined and the number of patients included into the study was powered based on a statistical calculations taking into account the previously published studies on portable devices. We used the Kruskal-Wallis test to compare the study sites. A p values less than 0.05 was considered significant. All analyses were performed with the R software v 3.5.0.

Results

Patients

Eighty-six patients were enrolled in the study; however, only the data of 78 patients were used for analysis because five patients withdrew consent and data for three patients were missing due to wi-fi connection problems. The clinical data of all participants are presented in Table 2. Of the 78 patients, 21 (27%) adhered to the requirement for using the device daily throughout the study (21 ± 3 days). The number of measurements performed, both acceptable and incorrect, differed significantly between the study sites ($p = 0.028$, Figure 1).

Primary end point

Of the 78 patients, 67 (86%) met the primary endpoint because they performed at least three acceptable measurements within seven days (±1 day) in any of the three weeks of the study. Figure 2 shows the percentage of patients who achieved the primary endpoint in each study site.

Table 2. Baseline characteristics of all ($n = 86$) enrolled participants.

Variable		Patients
Age [years]	mean (SD)	All patients 37.4 (11.4) Female 38.6 (10.4) Male 36.2 (12.1)
Gender	*n*	Female 41 (47%)
Systolic blood pressure [mmHg]	mean (SD)	121 (11)
Diastolic blood pressure [mmHg]	mean (SD)	75 (7)
Heart rate [beat per minute]	mean (SD)	74 (9)
Height [cm]	mean (SD)	174 (10)
Weight [kg]	mean (SD)	80 (17)
Respiratory rate [breaths per minute]	mean (SD)	15.2 (1.7)
Level of asthma control according to GINA	*n*	Controlled 27 (32%) Partly controlled 58 (67%) Uncontrolled 0 (0%)
Asthma duration [years]	mean (SD)	15.7 (13.3)
Comorbidities	*n*	allergy 42 (49%); allergic rhinitis 38 (45%) eye disorders 12 (14%); gastrointestinal diseases 6 (7%); diseases of the liver, pancreas, and biliary tract 6 (7%); skin diseases 6 (7%); musculoskeletal diseases 4 (5%); cardiovascular diseases 2 (2%); psychiatric diseases 2 (2%); hematological diseases 1 (1%); endocrine diseases 1 (1%); other 3 (3%).

GINA, Global Initiative for Asthma; SD, standard deviation.

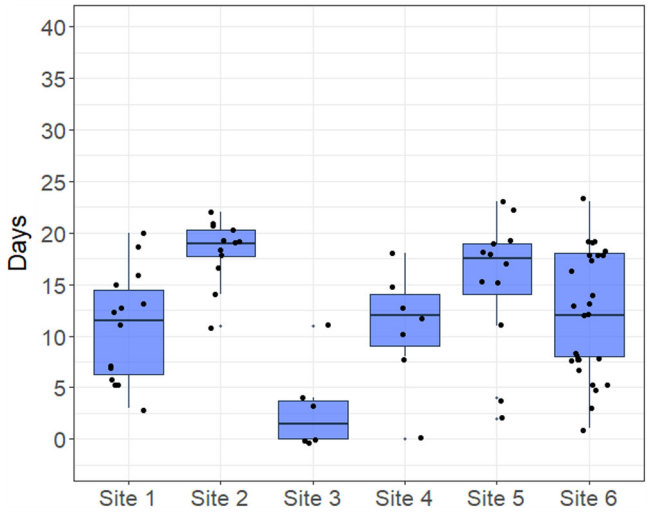

Figure 1. The mean number of days in which participants used the device correctly once or more for each study site (error bars represent 95% confidence intervals) ["number of days"/"sites"]. Dots represent data of individual patients.

Retraining

At enrollment, all subjects were trained and were able to perform accurate spirometry. Of the 62 patients (who used the device daily between enrollment and follow-up visit two to three days later and who also reported no technical difficulties with the device), 20 (32%) required retraining. Retraining was successful in 8 individuals. The number of patients requiring retraining differed between study sites, which may suggest that the quality of the maneuvers could depend on the quality of the first training.

Other measurements

Forty-four (56%) individuals achieved acceptable spirometry results at least 3 times within each week of the study (Figure 3). Seventy-five (96%) participants used the device correctly once or more, and 10 (13%) patients performed acceptable spirometry measurements every single day over the three-week follow-up, i.e. (0).21 consecutive days. Each day of the study, on average 68% of patients who conducted spirometry were able to perform an acceptable measurement (Figure 4). Nearly all patients reported their symptoms daily in the smartphone diary (96–100% for each day of the study).

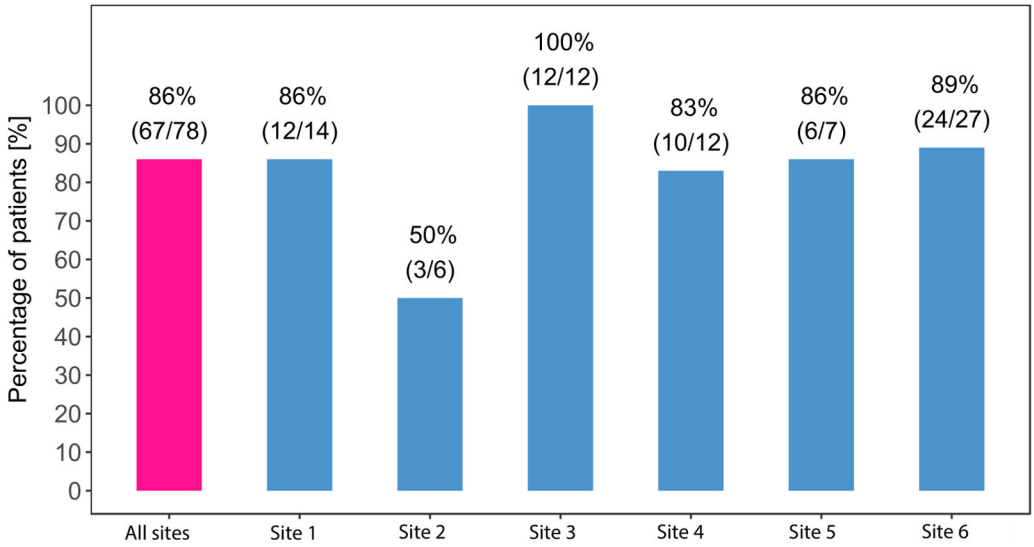

Figure 2. Percentage of patients who met the primary end-point ["Percentage of patients"/"sites"].

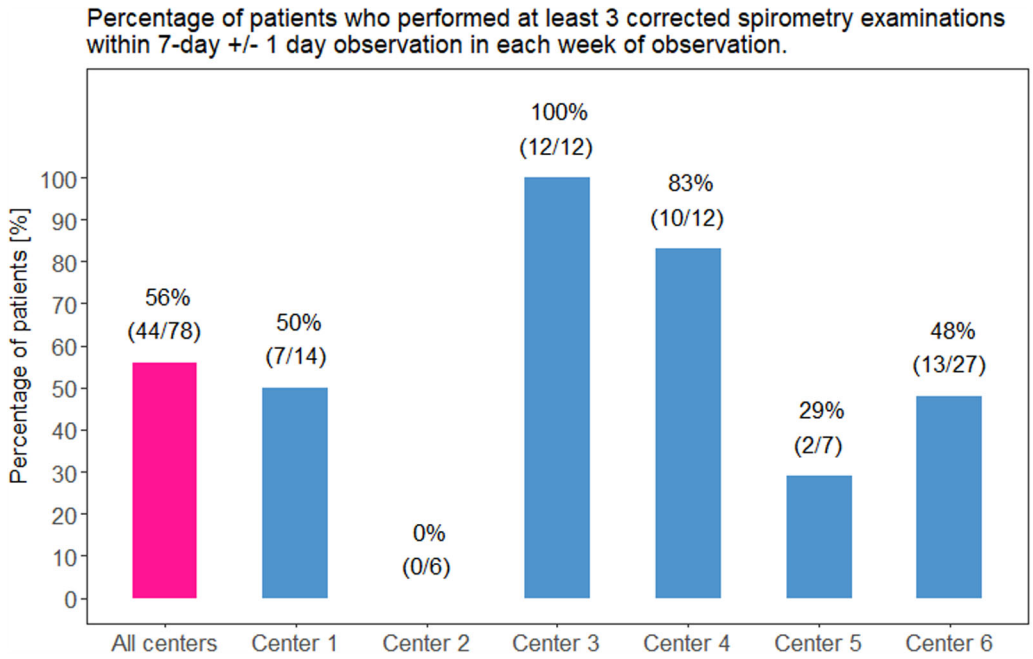

Figure 3. The percentage of patients who performed at least three acceptable spirometry measurements within seven days in each week of the study ["Percentage of patients"/"sites"].

Safety

There were no serious adverse events observed during the study. Five adverse events were recorded, including three upper respiratory tract infections and two technical difficulties in operating the device, which were not related to device malfunction.

Patient satisfaction

Most patients evaluated the device as good or very good at enrollment (89%, $n = 65$) and at the end of the study (87%, $n = 63$).

Discussion

In this pilot study, we assessed a new spirometry device for the self-monitoring of asthma control, which in the long term could improve asthma self-management and thus help to reduce asthma-related hospitalizations and deaths. The study showed that unsupervised home spirometry with the AioCare® system is safe and feasible in patients with asthma. Fifty-six percent of the patients were able to perform spirometry measurements of acceptable quality at least 3 times within 7 days in each week of the study, and 86% of all patients achieved the primary endpoint. There were no device-related adverse events.

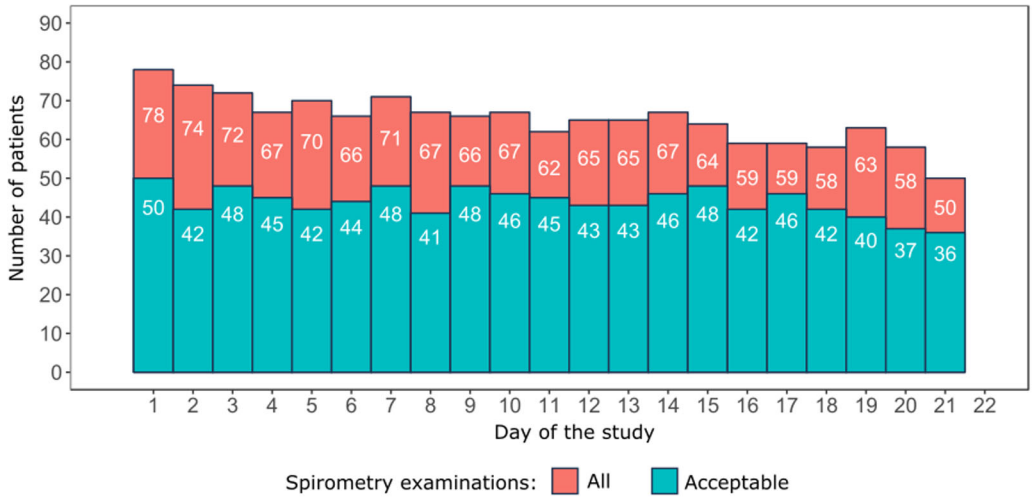

Figure 4. The number of patients who used the device once or more daily during the study. All measurements are marked in red, acceptable ones – in blue. ["number of patients"/"study day"].

Comparable success rates (according to ATS/ERS criteria) were observed for spirometry examinations performed at primary care settings, with majority of sessions classified as acceptable and reproducible. Healthcare professionals, who received more training than did the patients in our study, produced spirometry data that complied with the ATS/ERS criteria in 84% of sessions (10). In another primary practice-based study, depending on mode of spirometry delivery, 76% or 44% of tests met the ATS standards of acceptability and reproducibility (11). In our study, 86% of participants were able to perform spirometry measurements of acceptable quality on a regular basis using self-monitoring AioCare® device.

The AioCare® spirometer was used as per protocol on average 19 days within the three weeks of the study. Among 78 subjects, 58 (74%) performed spirometry examinations every day during 21 ± 3 days of the study (as was required by protocol). To further improve usage of the device, we plan to use reminders (such as short text messages). In comparison, patients with muscular dystrophy used a hand-held peak flow meter once or more in 80% of weeks during a 12-month study (12). Compared to that device, the AioCare® spirometer has an advantage, because it enables remote reminders via an integrated application, which could further increase patient adherence. The quality of instructions given to patients by investigators could be important as well. For example, in our study, patients from site 2 had substantially lower adherence than those from other sites (Figure 1), which could be due to poor instructions given to patients at enrollment. This lack of clear instructions could also be reflected by a lower percentage of patients who achieved the primary end point in site 2 (see Figure 2). There is no doubt that training and education is vital in all aspects of self-management and long-term monitoring of chronic diseases. We think that, when the device is used in clinical practice, it will be important to remind patients to take spirometry measurements daily to detect impending asthma exacerbations. In our study, about one-third of patients needed retraining, and a substantial fraction of individuals failed to succeed after retraining. Apart from retrainings, the percentage of acceptable spirometry measurements might be increased if certain improvements to the device software are applied, such as an intelligent spirometry assistant providing individualized hints for the patient regarding the measurement technique based on analysis of unsuccessful tests.

The AioCare® system may improve self-management of asthma, which is important because it may impact asthma control and significantly decrease the risk of hospital admission (13). Our findings show that the AioCare® system can be recommended for self-monitoring, because nearly all patients reported their symptoms daily in the smartphone application. Moreover, the AioCare® system enables tele-monitoring, which offers further support to patients with asthma (14). Making AioCare® data available to the physician, via tele-monitoring, can improve patient adherence. For example, when a patient fails to take spirometry measurements for several days, the physician, or an automated message from the system, could remind the patient that daily measurements are important for detecting impending asthma exacerbations. Thus, the AioCare® system may improve the patient-doctor partnership and be regarded as an educational tool. Importantly, previous studies showed that educating

patients with asthma on their disease improves asthma control and reduces the need for emergency services (15). The AioCare® system could also be used for spirometry monitoring in other lung diseases such as chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis, in which daily home spirometry helps to detect disease progression (16).

The AioCare® system used daily for three weeks was safe, with no adverse events related to the device. About 90% of patients were satisfied with the device throughout the study period.

Our study was limited by a small sample and short period and therefore could not detect whether the use of the AioCare® system prevents asthma exacerbations and improves other treatment outcomes. An efficacy trial for longitudinal outcomes of self-management based on the AioCare® system is planned.

In conclusion, home self-monitoring of asthma with a connected mobile spirometer is feasible, and it is associated with high patient satisfaction. Active contact between the physicians and appropriately instructed and motivated patients is important for obtaining reliable home spirometry measurements and may contribute to improved asthma outcomes.

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Disclosure statement

MK and PD are members of the Scientific Board of HealthUp; LK is the inventor of AioCare and a shareholder of HealthUp; MS is employed by HealthUp.

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