Home spirometry appears accurate and feasible for monitoring chronic respiratory disease

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To the Editor:

Spirometry remains the gold standard to diagnose and monitor respiratory disease [1]. However, limited access has been further exacerbated by restrictions introduced during the coronavirus disease 2019 pandemic. Underutilisation of objective testing with spirometry contributes to the misdiagnosis of respiratory diseases such as asthma and COPD [2, 3]. Home spirometry is accurate in patients with relatively normal lung function and may overcome some of the access, cost and infection-control barriers associated with in-clinic spirometry [4–8]. What remains uncertain is the accuracy and feasibility of home spirometry with newer ultrasonic devices across a spectrum of respiratory diseases. Furthermore, a recent systematic review suggested that unsupervised home spirometry underestimates forced expiratory volume in 1 s (FEV_1) and forced vital capacity (FVC) compared to supervised spirometry [9]. Therefore, this study assessed the accuracy and feasibility of ultrasonic home spirometers to monitor the lung function of patients with a range of respiratory diseases.

Ethics approval was obtained from Bellberry Limited (approval number 2022-03-293-A-6) and the study was registered on the Australian and New Zealand Clinical Trial Registry (ACTRN12623000559617). Subjects with doctor-diagnosed asthma, COPD, bronchiectasis and interstitial lung disease (ILD) were recruited on a voluntary basis from tertiary clinics at a public hospital and specialist private rooms. Healthy control subjects (without doctor-diagnosed respiratory disease) were recruited through advertising *via* a local university.

Subjects attended a clinic appointment where written consent was obtained. Technicians assessed subject lung function using a standard desktop spirometer (MCG Diagnostics, USA) and trained subjects to use a smartphone-connected ultrasonic home spirometer (SpiroHome; Inofab, Turkey). Subjects were coached and encouraged to meet American Thoracic Society (ATS) and European Respiratory Society (ERS) criteria [1]. No subjects withheld or altered their prescribed medication schedules.

Following the clinic assessment, subjects took the ultrasonic spirometer home and assessed their lung function within 24 h and thereafter twice weekly for 3 weeks. The timing of the test in relation to medications was not dictated, due to the risk of interference with medical management. The research team did not intervene during this period; however, the home spirometer software provided acceptability grading and error messages with each manoeuvre to prompt subjects to correct their technique. At the end of the 3-week testing period, subjects completed an exit survey to assess their perceived confidence using electronic technology and their willingness to use the spirometer as a part of their long-term care plan on ordinal scales.

77 subjects performed technically acceptable spirometry both in the clinical laboratory and home within 7 days of their clinic appointment. 16 subjects were not studied in the accuracy protocol due to 1) desktop spirometer equipment failure (n=12), and; 2) not assessing at home spirometry within 7 days of clinic appointment (n=4). 93 subjects conducted spirometry at home and contributed to survey responses. Analysis and graphical representation were conducted using GraphPad Prism (version 9.0, 2022; GraphPad, San Diego, CA, USA). Correlations between desktop and home spirometer FEV_1 and FVC were assessed using nonparametric Spearman's correlation and Bland–Altman analysis to assess the

Shareable abstract (@ERSpublications)
Spirometry is underutilised and can be difficult to access. This study assessed the accuracy and feasibility of home spirometry compared to gold standard. Findings suggest home spirometry is accurate and feasible across many respiratory disease groups. https://bit.ly/42TLoYd

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agreement between the two devices. Kruskal–Wallis ANOVA was used to compare error (relative to gold standard) produced by home spirometry (FEV_1 and FVC), and survey responses between disease groups. Changes in FEV_1 and FVC across home test sessions were quantified by coefficient of variation. Chi-squared test assessed the proportion of tests that met ATS/ERS criteria across clinic and home sessions.

Subjects (n=93) had a median (interquartile range (IQR)) age of 62.1 (23.8) years, and included healthy controls (n=19), subjects with doctor-diagnosed asthma (n=22), COPD (n=18), bronchiectasis (n=17) and ILD (n=17). 58% were female. There was a strong positive correlation between the desktop spirometer (supervised) and home spirometer (unsupervised) for both FEV_1 and FVC (r=0.97, p<0.0001; figure 1a,c). The home spirometer produced a slight underestimation of FEV_1 (−0.10 L; figure 1b) and FVC (−0.03 L; figure 1d), a bias that was within narrow limits of agreement. These results did not significantly differ with removal of healthy control data. The error (relative to gold standard) produced by home spirometry was similar across the control and the disease groups for FEV_1 and FVC (p=0.40 and p=0.27, respectively).

Subjects conducted home spirometry twice weekly over 3 weeks with a median (IQR) 7.0 (2.5) tests conducted. There was no change in the proportion of tests performed that met ATS/ERS criteria in the clinic or the home environment (p=0.48). Approximately 97% of subjects completed more than two out of six home test sessions, with a coefficient of variation (95% CI) for FEV_1 of 6.1% (2.8–8.2%) and 4.7% (2.5–5.9%) for FVC. This analysis indicates stable spirometric parameters over the home testing period, which is influenced by subject competence and temporal change in lung function. Exit survey responses

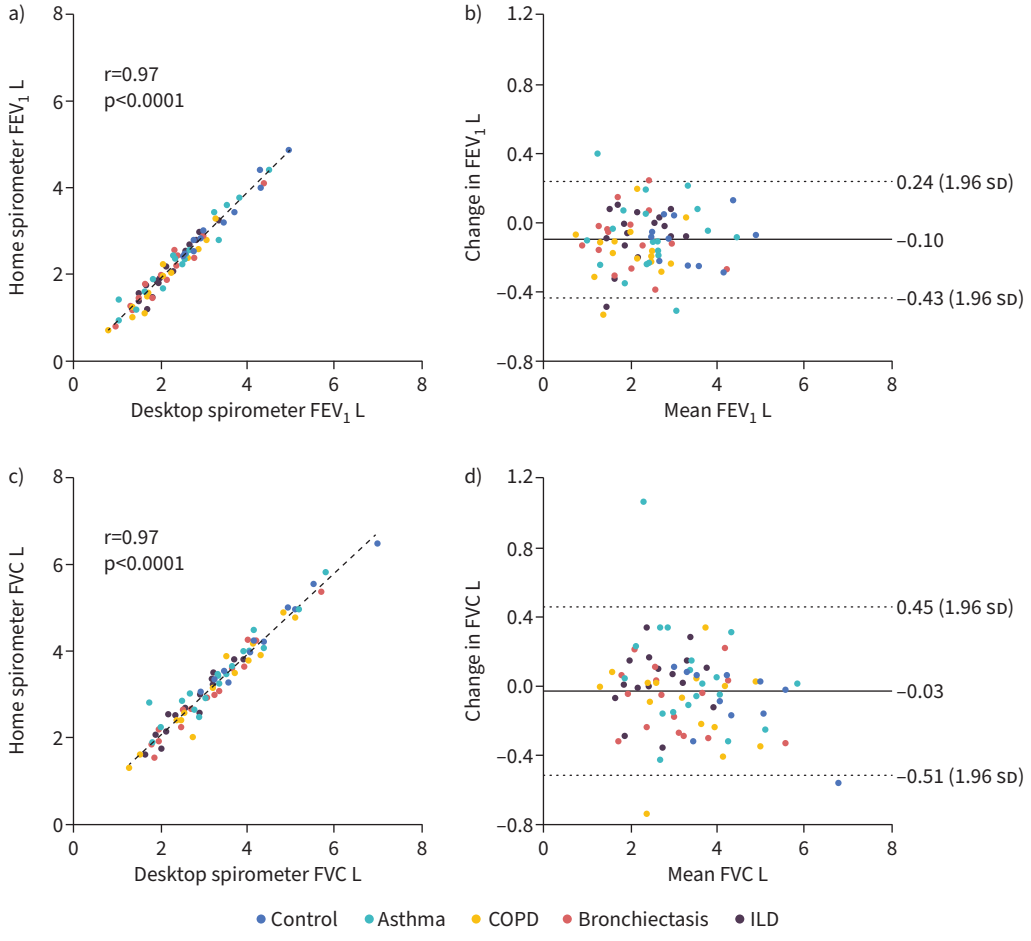

FIGURE 1 A strong positive correlation was observed between values obtained by desktop (in-clinic) and home spirometer (at home) for a) forced expiratory volume in 1 s (FEV_1) and c) forced vital capacity (FVC). Bland–Altman analysis of b) FEV_1 and d) FVC. Difference is computed as home minus desktop spirometry. A good agreement was observed between the two devices (n=77). ILD: interstitial lung disease.

assessing subject's confidence in using electronic technology and willingness to use home spirometer as part of their long term care was "strongly agree" for both (p=0.73 and p=0.64, respectively).

In this study, we determined that home spirometry appears to be an accurate and feasible method for assessing lung function in patients with chronic respiratory disease. Initial assessment considered the accuracy of desktop spirometry conducted in the clinic compared to at-home spirometry. We observed good agreement between desktop and home spirometry. Our findings were similar to studies using the same ultrasonic device for individuals with milder airflow abnormalities and whose home spirometry was supervised [4, 10]. The close correlation identified in this study could be attributed to multiple factors: ultrasonic devices may have reduced risk of mechanical errors compared to turbine spirometers, the assistive software provided participants with video tutorials and test grading, and the motivated, health-literate participants who volunteer for research.

The strengths of this study were the use of "real-world" specialist clinic patients, and the clinically meaningful comparison of supervised in-clinic desktop spirometry with unsupervised home spirometry [11]. We acknowledge that while subjects had high compliance when conducting home spirometry without any prompting or coaching from the research team, this may not be fully representative of all clinic attendees. Lung function parameters assessed by spirometry were also relatively consistent across the six home test sessions, but it is unclear if this would be maintained over a longer trial, and of course variability in lung function is expected with disease and associated management strategies. However, it is important to appreciate that adherence with interventions has been shown to decline over extended home testing periods [12].

It is essential that there is greater availability of spirometry for the diagnosis and monitoring of common respiratory diseases. Unsupervised home spirometry appears to be an important tool to increase the penetration of lung function testing. Introduction of home spirometry is applicable to individuals who are isolated geographically, of particular relevance in our state, which is a similar size to western Europe. However, many individuals may favour home testing because of limitations impeding travel to the hospital, or competing home or work commitments. Home spirometry may also alleviate some infection control concerns around respiratory waiting rooms. We look forward to future studies trialling home spirometry in a bundle alongside video consultations and other remote monitoring to establish how these telehealth strategies can best be deployed in future, and whether they are cost-effective.

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Ethics statement: This project was a low-risk medical device observational study, which received ethics approval through Bellberry Limited (approval number 2022-03-293-A-6). This project was conducted in compliance with good clinical practice and the applicable regulatory requirements. Potential candidates were identified through tertiary hospital respiratory clinics and informed of the study. If willing, their details were provided to the research team for screening and recruitment. Healthy volunteers were recruited for the control group through the University of Western Australia through verbal and the university's crowd research platform. Researchers contacted potential candidates, provided information on the study, screened for eligibility and arranged an appointment if suitable. Written informed consent was obtained on the day of the attendance. Participants were asked to fill and submit a relevant medical history questionnaire and contact details on enrolment to the study. Participants were randomised into either desktop spirometer (control) or portable spirometer (device) first by sequence generated by the analysis programme SPSS (IBM) to avoid introducing bias from improved spirometry technique from repeated manoeuvres.

Conflict of interest: C.L. Wilson was awarded the Margaret Lowman-Hall honours scholarship stipend to undertake this project. She has no other conflicts of interest to declare. A. Cairncross has no conflict of interest to declare.

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