A Comparison of Clinic Versus Home Spirometry in the CAPTAIN Study

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DISCLOSURES

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- On behalf of all authors, an audio recording of this poster was prepared by Neil Barnes, who did not receive any payment for this recording.
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Objectives and methods

INTRODUCTION AND OBJECTIVES

- Many respiratory consultations are currently taking place virtually due to the ongoing SARS-CoV-2 pandemic, while traditional lung function testing in clinic is difficult to perform.
- Therefore, there is increasing interest in whether home measurements of lung function could be used in place of clinic testing. However, little is known as to whether home spirometry accurately reflects clinic measurements, and whether it provides sufficient precision to inform treatment decisions.
- We evaluated the agreement between home and clinic measurements of trough FEV₁ using data from the CAPTAIN study (N=2436) (205715; NCT02924688).

METHODS

- CAPTAIN was a Phase IIIA, randomized, double-blind, 24–52 week, parallel-group study in adults with inadequately controlled asthma despite ICS/LABA therapy.
- Trough FEV₁ measurements were taken in clinic at approximately the same time in the morning (MasterScope device); patients also took three measurements of trough FEV₁ each morning at home using a peak flow meter (AM3 device) and the highest valid measurement was recorded.
- The Bland-Altman method assessed agreement between clinic trough FEV₁ and the average of the home trough FEV₁ measurements collected on the same day and 2 days prior to the clinic measurement, at baseline and at Week 24 (post hoc analyses).

FP/SAL provided BID as a fixed dose via the DISKUS DPI; FF/VI and FF/UMEC/VI provided QD as a fixed dose via the ELLIPTA DPI. Patients had up to 5 on-treatment clinic visits. *All patients had a safety follow-up contact approximately 7 days after the End of Study Visit (Week 24, 36, or 52) or Early Withdrawal Visit; †daily FP >250 mcg or equivalent; ‡measurements were valid if breathing volume >0.47–<10 L, breathing flow >50 L/min, and FVC>FEV₁; At least one valid measurement had to be recorded at each timepoint for data to be stored on the AM3 device.

BID, twice daily; DPI, dry powder inhaler; FEV₁, forced expiratory volume in 1 second; FF, fluticasone furoate; FP, fluticasone propionate; FVC, forced vital capacity; ICS, inhaled corticosteroid; LABA, long-acting β₂-agonist; QD, once daily; SAL, salmeterol; UMEC, umeclidinium; VI, vilanterol.

Addition of UMEC 62.5 mcg to FF/VI was associated with improvements in both clinic (A) and home (B) trough FEV$_1$. 

- Improvements were seen early after randomization and were maintained to the end of the treatment period.
Agreement between clinic and home trough FEV₁ measurements was poor at baseline (A) and Week 24 (B)

- The lower and upper limits of agreement were -0.812 L and 0.943 L, respectively, at baseline and -0.771 L and 0.980 L, respectively, at Week 24.
- In total, 6% of patients were outside the limits of agreement at baseline (n=151) and Week 24 (n=143).

Bland-Altman plots comparing clinic versus home trough FEV₁. Home trough FEV₁ was derived by taking the average of the home trough FEV₁ measurement collected on the same day as clinic trough FEV₁ and 2 days prior. Patients were required to have a value for both clinic and home trough FEV₁ to be included (baseline: n=2434, Week 24: n=2261). Baseline clinic trough FEV₁ is the last acceptable/borderline acceptable measurement prior to randomized treatment start.

FEV₁, forced expiratory volume in 1 second

The lack of agreement between home and clinic spirometry measurements in the CAPTAIN study suggests that home spirometry performed with the AM3 device cannot be used as a surrogate for clinic spirometry measures.

– Therefore, caution should be exercised when using home spirometry data in research or clinical care.

The reason for the lack of agreement between home and clinic trough FEV₁ measurements is not clear.

– Possible explanations include the different devices and methodologies, and lack of supervision and coaching for home measurements.

Despite this lack of agreement between the two measures, addition of UMEC to FF/VI led to consistent improvements in lung function in patients with uncontrolled asthma on ICS/LABA, irrespective of the spirometry measure used.

It is possible that home spirometry may provide different and potentially complementary information to clinic measurements; further investigation is warranted.
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