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A Comparison of Clinic Versus Home Spirometry in the CAPTAIN Study

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Recording by Neil Barnes

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DISCLOSURES

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- ELLIPTA and DISKUS are owned by or licensed to the GSK group of companies.
- 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

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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.[1] 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 FEV_1 using data from the CAPTAIN study (N=2436) (205715; NCT02924688).[2]

METHODS

Week	Period	Treatment
Week -5 Weeks -5 to -2	**Visit 1: Screening** 3-week run-in period	FP/SAL 250/50 mcg
Week -2 Weeks -2 to 0	**Visit 2: Enrollment** 2-week stabilization period	FF/VI 100/25 mcg
Week 0 Weeks 0 to 24	**Visit 3: Randomization** Fixed treatment period	FF/VI 100/25 mcg (N=407) FF/UMEC/VI 100/31.25/25 mcg (N=405) FF/UMEC/VI 100/62.5/25 mcg (N=406) FF/VI 200/25 mcg (N=406) FF/UMEC/VI 200/31.25/25 mcg (N=404) FF/UMEC/VI 200/62.5/25 mcg (N=408)
Week 24 Weeks 24 to 52	**Primary endpoint** Variable treatment period	
	1-week safety follow-up*	

- 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 FEV_1 measurements were taken in clinic at approximately the same time in the morning (MasterScope device); patients also took three measurements of trough FEV_1 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 FEV_1 and the average of the home trough FEV_1 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>FEV_1. At lest 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; FEV_1, forced expiratory volume in 1 second; FF, fluticasone furoate; FP, fluticasone propionate; FVC, forced vital capacity; ICS, inhaled corticosteroid; LABA, long-acting $ß_2$-agonist; QD, once daily; SAL, salmeterol; UMEC, umeclidinium; VI, vilanterol

1. Halpin DMG, et al. Respir Res 2019;20:159; 2. Lee LA, et al. Lancet Respir Med 2020;9:69–84.

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Addition of UMEC 62.5 mcg to FF/VI was associated with improvements in both clinic (A) and home (B) trough FEV_1

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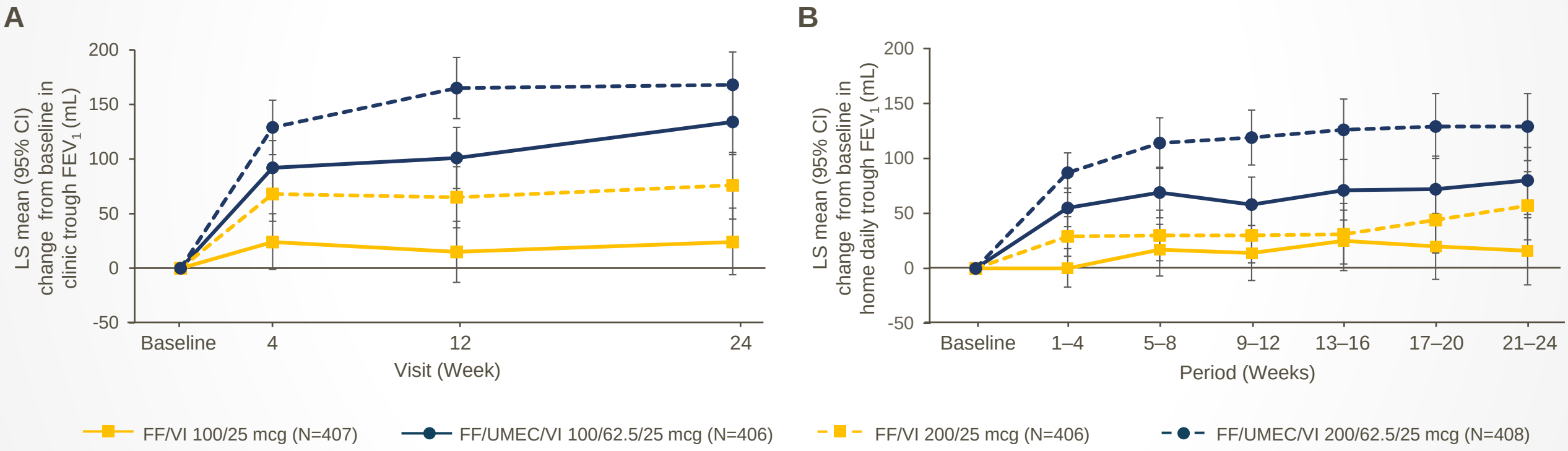
- Improvements were seen early after randomization and were maintained to the end of the treatment period.



Baseline clinic trough FEV_1 was the last acceptable/borderline acceptable measurement prior to randomized treatment start. Baseline home trough FEV_1 was the mean value over the last 14 days prior to randomized treatment start. Home spirometry was averaged over a 4-weekly period.

CI, confidence interval; FEV_1, forced expiratory volume in 1 second; FF, fluticasone furoate; LS, least squares; UMEC, umeclidinium; VI, vilanterol

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Agreement between clinic and home trough FEV_1 measurements was poor at baseline (A) and Week 24 (B)

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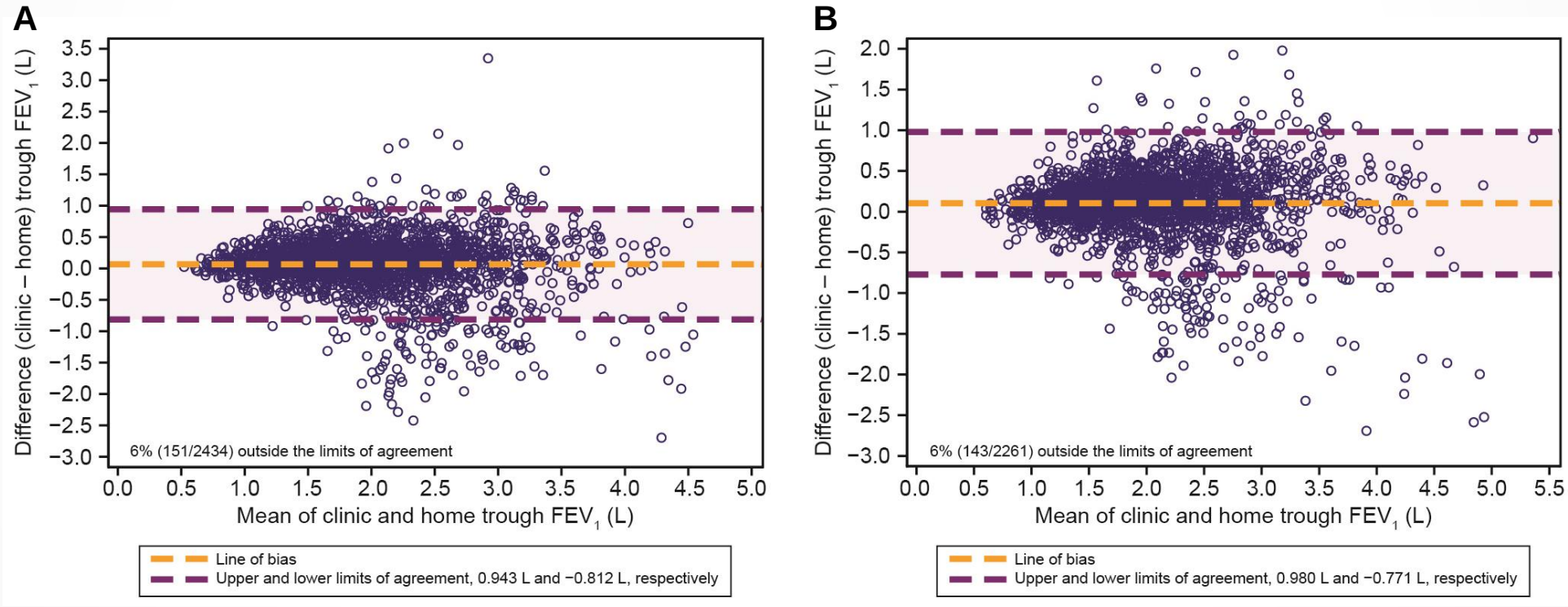
- The lower and upper limits of agreement were -0.812 L and 0.943 L, respectively, at baseline and -0.771 L and 0.980 L, respectively, at Week 24.
- In total, 6% of patients were outside the limits of agreement at baseline (n=151) and Week 24 (n=143).



Bland-Altman plots comparing clinic versus home trough FEV_1. Home trough FEV_1 was derived by taking the average of the home trough FEV_1 measurement collected on the same day as clinic trough FEV_1 and 2 days prior. Patients were required to have a value for both clinic and home trough FEV_1 to be included (baseline: n=2434, Week 24: n=2261). Baseline clinic trough FEV_1 is the last acceptable/borderline acceptable measurement prior to randomized treatment start.

FEV_1, forced expiratory volume in 1 second

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Conclusions

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- 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 FEV_1 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.

FEV_1, forced expiratory volume in one second; FF, fluticasone furoate; ICS, inhaled corticosteroid; LABA, long-acting ß$_2$-agonist; UMEC, umeclidinium; VI, vilanterol

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CO-AUTHORS' DISCLOSURES

- Z Bailes, A Fowler, F Gardiner, E Pizzichini, D Slade, and A Zarankaite are employees of GSK and hold stocks or shares in GSK.
- G Peachey is an employee of GSK and holds stocks or shares in GSK and Novartis.
- R Chaudhuri has received personal fees for advisory board meetings, speaker fees or conference travel from AstraZeneca, Chiesi, GSK, Novartis, and Teva, personal fees for conference travel from Boehringer Ingelheim and Napp Pharmaceuticals, and a research grant from AstraZeneca
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