Compliance Analysis for Remote Spirometry in Subjects with Mild to Moderate Asthma

RATIONALE

- Remote spirometry
  - May be convenient for patients
  - More frequent data collection
  - An option for patients during COVID-19 pandemic
  - Shown to be comparable with clinic spirometry in patients with asthma [a] and COPD [b]
- Concern: will patients perform spirometry remotely?

METHODS

- Remote spirometry data from 3 studies sponsored by Regeneron in patients with mild to moderate asthma (see table)
  - For Study 3: only data in treatment period (28 days) was analyzed to match timeframe in Studies 1 & 2
- All study subjects received
  - A dedicated iPhone 6
  - A Cohero Thor mSpirometer device that synchronizes with the BreatheSmart application on the smartphone
  - Training on how to perform pulmonary function tests (**PFTs**) remotely
- Instruction to perform PFTs at home at least twice daily at predefined time windows
  - Study 1: 6:00-12:00, 18:00-24:00
  - Study 2: 6:00-10:00, 18:00-22:00, (optional) 11:00-13:00
  - Study 3: 6:00-10:00, 18:00-22:00

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RESULTS

- Good compliance for remote spirometry data collection for 28-day period across 3 studies
  - Twice daily: 89% (2520 observed of 3024 expected PFTs)
  - Within predefined time windows: 85% (2240 of 3024 PFTs)
  - No missing day in 28-day period: 83% (2141 of 3024 PFTs)
  - Met all above compliance criteria: 56% (1693 of 3024 PFTs)
- Number of compliant subjects did not decline over the period of 28 days
- No difference in compliance stratified by morning/evening or weekend/ weekday

CONCLUSIONS

Remote spirometry data collection is feasible in studies recruiting asthma patients

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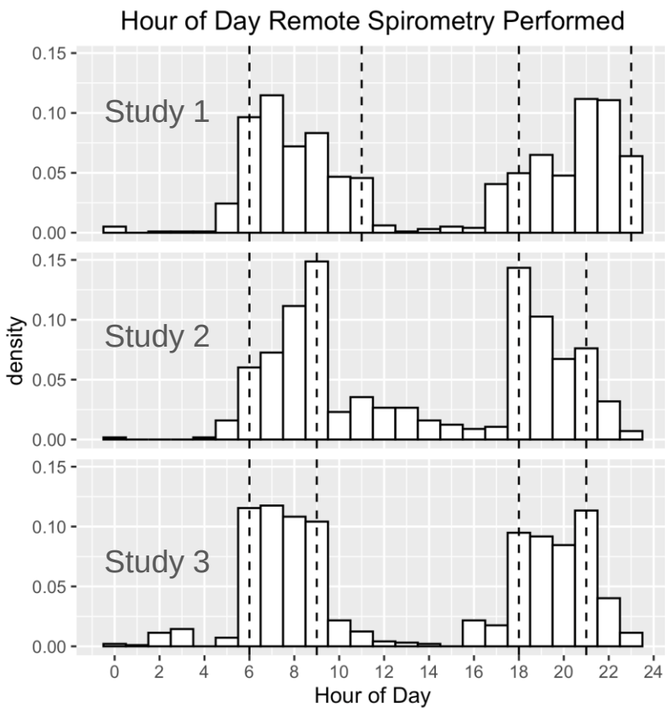
REFERENCE

a. Kerwin, E.M., Hickey, L. & Small, C.J. Relationship between handheld and clinic-based spirometry measurements in asthma patients receiving beclomethasone. *Respir. Med.* **151**, 35–42 (2019).

b. Rodriguez-Roisin, R. *et al*. Daily home-based spirometry during withdrawal of inhaled corticosteroid in severe to very severe chronic obstructive pulmonary disease. *Int. J. Chron. Obstruct. Pulmon. Dis.* **11**, 1973–1981 (2016).

	Study 1	Study 2	Study 3	All 3 Studies
Study Type	Observational	Observational	Interventional	
Country	US	UK	UK	UK / US
Duration	28 Days	28 Days	6 Months	28 Days
#Sites	1	1	3	5
#Subjects	20	12	22	54
Sex: Female	9	4	11	24
Sex: Male	8	8	11	27
Sex: Unknown	3	0	0	3
Age: Mean	39.5	41.1	42.4	41.0
Age: SD	11.4	9.9	10.1	10.4
Age: Min	24	26	21	21
Age: Median	37.5	40	43	41
Age: Max	60	55	59	60



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