

Relationships between same-day FVC and FIVC from forced spirometry and IVC from DLCO; findings in an IPF clinical trial

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Rationale

The 2019 ATS/ERS Spirometry Standards¹ strongly recommend the collection of a FIVC upon the completion of the forced exhalation. The FIVC should not exceed the FVC by the larger of 0.100 L or 5% of the FVC to confirm the forced exhalation started from full inflation. The 2017 ATS/ERS DLCO standards² specify the IVC of DLCO test gas should not be less than 90% of largest VC measured that day. We examined the relationship between these three parameters in an ongoing clinical trial for IPF.

Methods

We evaluated 340 same-day measurements of forced spirometry and DLCO from 153 patients in an ongoing clinical trial for IPF.

Results: Relationship between FIVC and FVC

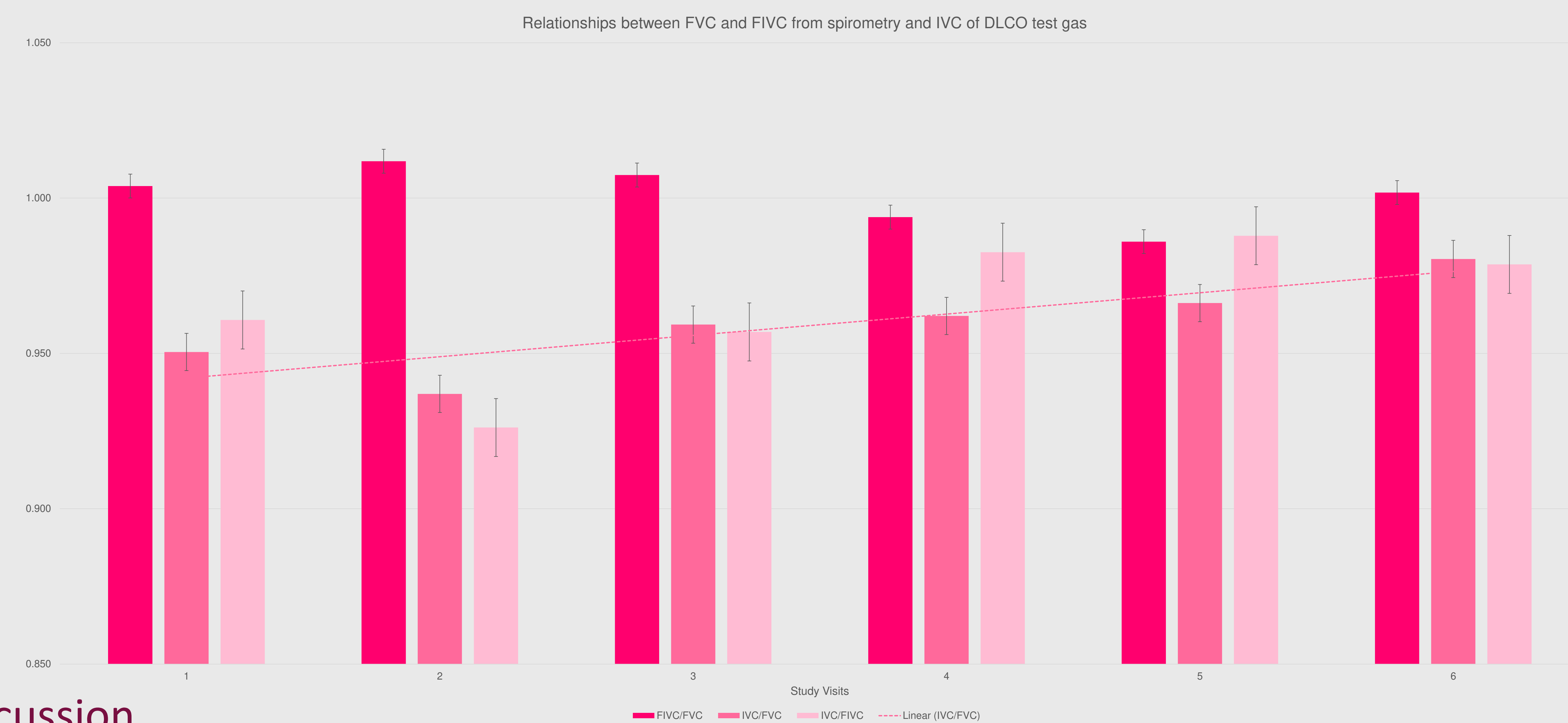
FVC >2.00L: 276 measurements showed a FVC > 2.00L. Of these, the FIVC was not properly performed and could not evaluate full inflation in 18 (6.5%). 172 measurements (76.1%) showed a FIVC indicating the forced exhalation started from full inflation. 36 measurements (10.5%) showed FIVC/FVC >1.05, indicating the forced exhalation started before full inflation was reached. 13 of these showed the FIVC was < 0.150L (mean 0.14L \pm 0.01L) larger than the FVC, less than the expected repeatability of FVCs. The mean FVC of these 13 measurements was 2.35L \pm 0.24 L

FVC <2.00L: 114 measurements showed a FVC \leq 2.00L. Of these, the FIVC was not properly performed in 3 measurements. Full inflation was demonstrated in 101 (88.6%) of these measurements. 7 measurements showed the FIVC exceeding the FVC by 0.100L. Of these, 4 showed the FIVC to be less than 0.150L larger than the FVC.

Results (cont.) Relationship between IVC in DLCO and FVC and FIVC

The IVC in 249 DLCO measurements (73.2%) was \geq 90% of the FVC. The IVC in 91 measurements (26.8%) was less than 90% of the FVC. The IVC/FVC in those 91 measurements averaged 0.81, \pm 0.08 and the absolute volume difference between the IVC and FVC was -0.44L \pm 0.25L.

Trending over time is limited by the number of patients completing later study visits. There was a small downward trend in the FIVC/FVC relationship as the study progressed suggesting the operators were doing better at coaching to full inflation. There was a slight upward trend in the IVC/FVC relationship as the study progressed (trend line, below), suggesting the operators were coaching better emptying or full inflation of the DLCO test gas, or both.



Conclusion/Discussion

The requirement to demonstrate full inflation during spirometry is achievable by most patients in this patient population and most sites quickly became accustomed to coaching the FIVC after FVC.

The allowable maximum difference between FIVC and FVC may be too low for patients with low FVCs. Studies may benefit if the limit was raised to 0.150L, the current repeatability tolerance for FVC.

Operators did poorly in coaching patients to meet the minimum test gas volume requirement during the DLCO test. 27% of DLCO measurements failed to meet the minimum inspired volume requirement. Focused training on coaching complete expiration and full inspiration may help.

References

1. Graham BL, et al. Standardization of spirometry, 2019 update. Official ATS and ERS Technical Statement. Am J Respir Crit Care Med. 2019
2. Graham BL, et al. 2017 ERS/ATS standards for single-breath carbon monoxide uptake in the lung. European Resp J. 2017