Is onsite spirometry quality Predicting the Quality of Home Spirometry?

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INTRODUCTION

High quality spirometry data in clinical trials is important for the assessment of efficacy, relevant clinical decision guidance and safety monitoring. Spirometry is effort-dependent and requires a correct technique to obtain clinically relevant measurements.

Therefore, the quality of FEV1 and FVC measurements is assessed based on ATS/ERS quality guidelines.

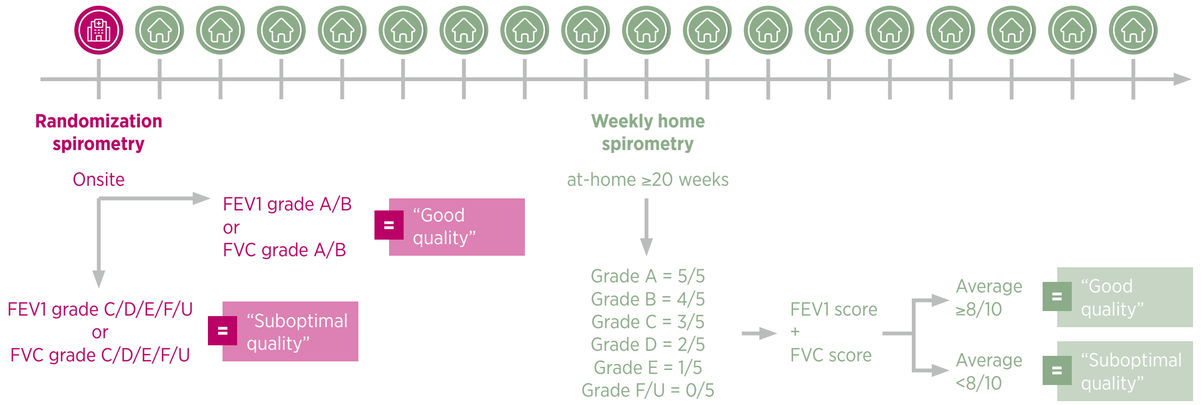
Home spirometry is a viable alternative or promising additional assessment in respiratory clinical trials. It can provide more frequent evaluation of lung function parameters and has a potential to reduce patient burden by limiting number of on-site visits. Home spirometry is performed by patients at home, without the supervision of skilled technician, therefore, efficient quality monitoring is important.

OBJECTIVES

This analysis aimed to determine **whether the quality of a patient's onsite spirometry could predict the quality of his/her home spirometry.**

METHOD

On-site spirometry data from 55 randomized patients performed at randomization visit was available at the time of analysis, followed by weekly home spirometry (unsupervised) for at least 20 weeks. The quality of onsite and home spirometry was assessed post-hoc using AI-based software (ArtiQ.QC v1.5.0, ArtiQ NV, BE). The session was classified as good quality if both FEV1 and FVC were classified as A or B, according to ATS/ERS standards. For home spirometry, the average quality over time was considered. Significant differences are checked with Fisher test (p-value < 5%)



RESULTS

Onsite spirometry \ Home spirometry	Good quality N	Suboptimal quality N	Total
Good quality	**26**	**16**	42
Suboptimal quality	4	**9**	13
Total	30	25	55

Table 1: Comparison of onsite spirometry and home spirometry quality in 55 patients (good quality: both FEV1 and FVC = A or B)

CONCLUSION

- 76.4% of patients had good-quality onsite spirometry as assessed by AI based software
  - ▶ 62% continued to perform good quality spirometry at home
- 23,6% of patients had suboptimal-quality onsite spirometry
  - ▶ 31% were able to perform good-quality spirometry at home

A Fisher test (alpha = 5%) showed that this result is close to statistical significance (p=0.062). Further analysis with more data is required.

We demonstrated that the quality of onsite spirometry could be one of the indicators of the quality of subsequent home spirometry maneuvers.
This shows the potential of AI-based software for flagging patients that would equire more training and follow-up during home spirometry measurements.

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