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Title: CT scans and patient selection: upper lobe predominant method is preferred to the heterogeneous method for emphysema categorization

Steven C Springmeyer, MD¹, David H Dillard, BS¹, William A Sirokman, BS¹ and Xavier Gonzalez, MD¹. ¹Clinical Research, Spiration, Inc., Redmond, Washington, United States of America.

Body: There are not uniform methods for using CT scans to separate and categorize subjects with emphysema for clinical trials. Lung Volume Reduction Surgery (LVRS) trials began with selecting subjects with heterogeneous rather than homogeneous emphysema. The NETT trial added the method (UL) for upper lobe predominant emphysema and non-upper lobe predominant emphysema. The UL method to categorize upper lobe predominant emphysema became important since this method, not the heterogeneous and homogenous method (HM), was useful to define the most favorable subgroup for LVRS. We have ongoing clinical studies with a bronchoscopic approach (Spiration IBV Valve) for the treatment of emphysema. Although valve treatment is different from surgery, patient selection and categorization based on CT scanning is important. The UL method uses a direct comparison of lung regions. The HM method uses a 5-point visual scoring system at three levels and defines the terms based on differences in scores. CT scans were read using UL at 6 sites and read again by one general radiologist (GR) and two academic thoracic radiologists (TR) with both UL and HM methods. 27 CT scans were available in digital format. All 27 were reviewed by TR and 15 by GR. The HM method had scoring variability with 8 disagreements between the TR and all cases scored different by the GR. The UL method showed 100% agreement between the sites, the GR, and one TR. The other TR disagreed on one CT on one subject. We conclude that the upper lobe predominant (UL) method, which guides LVRS selection in the US, gives more reproducible results, allows broader use, and is the preferred method.