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Title: Differences in clinical features and biomarkers of subsequent acute cystic fibrosis pulmonary exacerbations - Analysing exacerbations as separate entities

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Body: Background: Adult cystic fibrosis (CF) patients often suffer repeated acute pulmonary exacerbations (PExs). As CF is a relatively uncommon disease, previously published studies in the literature have included more than one exacerbation per patient in their data set and considered individual exacerbations of the same patient as separate entities. The validity of this approach has not yet been examined. Materials & Methods: This was a prospective study. Adult CF patients were included if they experienced 3 PExs treated with intravenous antibiotics in one year. Features of PExs included in the analysis were: CF symptom score, spirometry, oxygen saturation, heart rate, body mass index, C-reactive protein, and the time until the next exacerbation. For each parameter, comparisons were made by plotting differences against average using Bland and Altman method. The number of points where differences fell within and outside the 2 standard error of the mean (SEM) from equality were identified. Results: A total of 93 PExs in 31 patients (15 females) were analysed. Percentage of data that fell outside SEM ranged between 20% for BMI to 80% for the time until the next exacerbation. Minimal clinically important differences were also found in at least 40% of pairs of PExs for symptom score, CRP and spirometry measurements. Conclusions: Features of successive PExs differed in the same individual. The findings of this study lends support to considering acute CF pulmonary exacerbations to be separate entities in selected research projects.