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From the authors

We read with interest the comments by L.M. Fabbri and A. Augusti on our article entitled "INSTEAD: a randomised switch trial of indacaterol *versus* salmeterol/fluticasone in moderate COPD" [1]. However, we believe that those comments go well beyond the conclusion of the study, which is well supported by the data.

The Indacaterol: Switching Non-exacerbating Patients with Moderate COPD From Salmeterol/Fluticasone to Indacaterol (INSTEAD) trial examined a population of chronic obstructive pulmonary disease (COPD) patients with moderate airflow limitation [2], without a history of exacerbations in the previous year, and on treatment with inhaled corticosteroids (ICS)/long-acting β-agonist (LABA) combination therapy for ⩾3 months. After randomisation, 250 patients continued and completed 6-month treatments with salmeterol/fluticasone fixed-dose combination (SFC), while 246 patients completed 6-month treatments with indacaterol monotherapy, after switch from SFC without a washout period. The study data showed no difference in lung function (forced expiratory volume in 1 s (FEV_1) in the whole population and inspiratory capacity in a subgroup), symptoms, quality of life or exacerbations between the two arms and the two therapy regimens. The conclusion of the study, which is difficult to challenge, was that the population of COPD patients in the INSTEAD study does not need ICS, and that ICS can be safely withdrawn, if that treatment was initiated. In fact, according to COPD management guidance, these patients should not receive ICS in addition to their maintenance treatment with long-acting bronchodilators [3]. The results of our study should be evaluated for the recruited population and not for patients with either more severe COPD or frequent exacerbations, or both. It is important to emphasise that INSTEAD excluded COPD patients with severe airflow limitation (FEV_1 <50% predicted) and patients with exacerbations in the previous year, *i.e.* grades III and IV [2]. Clearly, any history of either asthma or like-asthma symptoms was in the exclusion criteria [1]. The INSTEAD randomised trial confirms the results of a recent real-life study on >800 moderate COPD patients [4], and supports the current management guidance on moderate COPD without history of exacerbations [3]. Were the patients in INSTEAD exacerbation-free in the previous year because they were treated with ICS? It seems very unlikely, because they did not exacerbate when ICS was withdrawn. After careful reading we do not see any significant discrepancy between the conclusion of INSTEAD and the recommendation of a recent editorial [5]. Clearly, the appropriate use of ICS in COPD is an important issue [5]. In fact, the possible benefit of ICS on airway inflammation [6] and exacerbation rate was found to be associated with side-effects [7, 8].

Any speculation on longer-term effects of indacaterol, and on the impact of ICS withdrawal in severe COPD patients with history of exacerbations, goes well beyond the purpose, the design, and the data of the INSTEAD study, but is explored in other trials [9, 10]. Likewise, we do not make any over interpretation either of the potential benefits of ICS in severe "frequent exacerbators" COPD patients [11] or on the use of the ICS/LABA combination in patients with the so called "asthma-COPD overlap syndrome" [5], although it might be a very interesting debate [12, 13].

We believe that INSTEAD data provides a significant contribution to the debate on the appropriate use of ICS in COPD patients [3, 14].

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This study shows that inhaled corticosteroids are not needed in COPD patients at low risk of exacerbations http://ow.ly/IkmDF

Andrea Rossi[1], Thys van der Molen[2], Ricardo del Olmo[3] and Luis Wehbe[4]
[1]Pulmonary Unit, University of Verona, Verona, Italy. [2]University Medical Center Groningen, University of Groningen, Groningen, The Netherlands. [3]Fundación CIDEA and Hospital Maria Ferrer, Buenos Aires, Argentina. [4]Fundacion Enfisema, Buenos Aires, Argentina.

Correspondence: Andrea Rossi, University and General Hospital Verona, Pulmonary Unit, Piazzale Stefani 1, Verona, 37126, Italy. E-mail: andrea.rossi_03@univr.it

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Sleep medicine certification for physicians in Spain

To the Editor:

Sleep medicine is a rapidly growing field. At present, there is a lack of standardisation and the quality of clinical decisions may vary widely. The best way to resolve this problem is to establish a procedure for certification, for both centres and physicians [1]. However, the implementation of a procedure of this kind is difficult, for a variety of reasons; for example, the wide range of criteria applied by different professional societies and the apparent perception that sleep diseases belong to different medical specialties. To date, several procedures have been developed to perform the certification process. In some countries, for instance, the USA [1–3], sleep medicine is considered an independent medical subspecialty, and in Germany [4, 5] and Saudi Arabia [6], its status as a subspecialty has been officially acknowledged. In other