

- 3 Celli BR, Thomas NE, Anderson JA, *et al.* Effect of pharmacotherapy on rate of decline of lung function in chronic obstructive pulmonary disease: results from the TORCH study. *Am J Respir Crit Care Med* 2008; 178: 332–338.
- 4 Jenkins CR, Jones PW, Calverley PM, *et al.* Efficacy of salmeterol/ fluticasone propionate by GOLD stage of chronic obstructive pulmonary disease: analysis from the randomised, placebo-controlled TORCH study. *Respir Res* 2009; 10: 59.
- 5 National Institute for Health and Clinical Excellence (NICE). Chronic Obstructive Pulmonary Disease. Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care. NICE, 2010. Available from: www.nice.org.uk/guidance/cg101
- 6 Qaseem A, Wilt TJ, Weinberger SE, *et al.* Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med* 2011; 155: 179–191.
- 7 Global Initiative on Obstructive Lung Disease. Global Strategy for Diagnosis Management and Prevention of Chronic Obstructive Pulmonary Disease. Global Initiative on Obstructive Lung Disease, 2014. Available from: www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html
- 8 Agusti A, Fabbri LM. Inhaled steroids in COPD: when should they be used? *Lancet Respir Med* 2014; 2: 869–871.

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From the authors

We read with interest the comments by L.M. Fabbri and A. Agusti 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 (FEV₁) 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 (FEV₁ <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>

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References

- 1 Rossi A, van der Molen T, del Olmo R, *et al*. INSTEAD: a randomised switch trial of indacaterol *versus* salmeterol/fluticasone in moderate COPD. *Eur Respir J* 2014; 44: 1548–1556.
- 2 Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management and Prevention of COPD. 2010. Available from: http://www.goldcopd.org/uploads/users/files/GOLDReport_April112011.pdf Date last updated: April 11, 2011. Date last accessed: Oct 14.
- 3 Calverley PMA. What to use INSTEAD of inhaled corticosteroids in COPD? *Eur Respir J* 2014; 44: 1391–1393.
- 4 Rossi A, Guerriero M, Corrado A, *et al*. Withdrawal of inhaled corticosteroid can be safe in COPD patients at low risk of exacerbation: a real-life study on the appropriateness of treatment in moderate COPD patients (OPTIMO). *Respir Res* 2014; 15: 77.
- 5 Agustí A, Fabri LM. Inhaled steroids in COPD: when should they be used? *Lancet Respir Med* 2014; 2: 869–871.
- 6 Lapperre TS, Snoeck-Stroband JB, Gosman MME, *et al*. Effect of fluticasone with and without salmeterol on pulmonary outcomes in chronic obstructive pulmonary disease: a randomized trial. *Ann Int Med* 2009; 151: 517–527.
- 7 Calverley PMA, Anderson JA, Celli B, *et al*. Salmeterol and fluticasone propionate and survival in chronic obstructive pulmonary disease. *N Engl J Med* 2007; 356: 775–789.
- 8 Suissa S. Number needed to treat in COPD: exacerbations *versus* pneumonias. *Thorax* 2013; 68: 540–543.
- 9 Wouters EFM, Postma DS, Fokkens B, *et al*. Withdrawal of fluticasone propionate from combined salmeterol/fluticasone treatment in patients with COPD causes immediate and sustained disease deterioration: a randomised controlled trial. *Thorax* 2005; 60: 480–487.
- 10 Magnussen H, Disse B, Rodriguez-Roisin R, *et al*. Withdrawal of inhaled glucocorticoids and exacerbations of COPD. *N Engl J Med* 2014; 371: 1285–1294.
- 11 Hurst JR, Vestbo J, Anzueto A, *et al*. Susceptibility to exacerbation in chronic obstructive pulmonary disease. *N Engl J Med* 2010; 363: 1128–1138.
- 12 Fabbri LM, Romagnoli M, Corbetta L, *et al*. Differences in airway inflammation in patients with fixed airflow obstruction due to asthma or chronic obstructive pulmonary disease. *Am J Respir Crit Med* 2003; 167: 418–424.
- 13 Contoli M, Baraldo S, Marku B, *et al*. Fixed airflow obstruction due to asthma or chronic obstructive pulmonary disease: 5-year follow-up. *J Allergy Clin Immunol* 2010; 125: 830–837.
- 14 Corrado A, Rossi A. How far is real life from COPD therapy guidelines? An Italian observational study. *Respir Med* 2012; 106: 989–997.

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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