Reviewer's report

Title: Extrafine Beclomethasone/formoterol compared to Fluticasone/salmeterol Combination Therapy in COPD

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Reviewer: Nikos Siafakas

Reviewer's report:

This study of Singh et al compares BDP/FF extafine to FP/S in COPD. It is reports that both treatments had equivalent effects on TDI (Transition Dyspnea Index) but BDP/FF was superior to changing FEV1.

It is surprising that the authors had as primary end-point TDI? It seams to me that this paper has been written after the results were analyzed. It is peculiar to set TDI equivalence and FEV1 superiority as the investigatory primary end points??

However, the overall methodology is the proper one!

The results showed the well known faster action of FF vs. Salmeterol.

However, the authors made a number of assumptions that the differences in TDI or SGRQ were due to ICS (discussion). It is well known that, mainly the LABA’S affect dyspnea via their action on hyperinflation mechanism and this improves SGRQ.

The author also speculates that the faster action of FF improves exercise tolerance but their results showed equivalence at 6 MWT (Discussion)

In addition, it is wrong to speculate that “Lower ICS dose provides functional improvement in exercise capacity”. The improvement in exercise capacity same in both arms, is due to reduction of hyperinflation and nothing to do with ICS!!

References are used to support their arguments in a rather general crude manner for example ref 11 does not study extrafine formulation.

Only approximately 50% of the subjects had FEV1<50% pred and less than 1 exacerbation Stage C the rest were stage A or B and the use of ICS on those are not strongly indicated by GOLD?? (discuss)

Figures and Tables:

OMIT figure 4, is similar to Fig 3 and discussed in the text (no data showed of subjects FEV1<50% pred in the tables (only in the Appendix)

Figure 2 Connecting arrows at the top of the bars to show the p value (p>0.05) is needed

Figure 5 Same connecting arrows at the two tops of the bars with p values are needed to demonstrate the difference, even better.

Table IA = SGRQ and its domains, look different between these two groups. This
may had affected the results showing in table 2A?? Please comment.

Level of interest: An article of importance in its field

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests