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Considerations of a real life pragmatic clinical trial in adolescent asthma

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We appreciate the interest shown by Van Boven and colleagues in our study. PACT (1) was first and foremost designed as a pragmatic randomized controlled trial (RCT) reflecting current UK primary care practice. While addition of controller treatment for those in the personalized care group with poor control was guided by the study algorithm the decisions with respect to monotherapy vs combination therapy, inhaler type and use of a spacer was down to the discretion of the participants primary care team.

In the personalized care group at 12 month follow-up 19/104 (18.3%) were prescribed ICS/LABA with and 25/104 (24%) ICS/LTRA. In the standard care group at 12 month follow-up 29/108 (26.9%) were prescribed ICS/LABA and 18/108 (16.7%) ICS/LTRA. We do not have data with respect to inhaler education practises or medication adherence due to the
pragmatic nature of the study design, but on balance we feel such potential confounders might be expected to be similar in both arms. Whether or not the 8.6% lesser use of ICS/LABA and 7.3% higher use of ICS/LTRA in the personalized therapy group would bias the results to a clinically meaningful degree is debatable.

There is long-running discussion with respect to the virtues and limitations of the differing study designs employed in trials assessing asthma management (2). PACT as a pragmatically designed RCT thus has notable limitations as detailed, however, its primary strength is in the relation to the ability to elucidate the potential effect of genotype directed prescribing in the real-life clinical setting of primary care, increasing the external validity of the findings and obtaining conclusions that are relevant to clinical practice (3-5). We therefore retain faith in the validity of our results and their generalisability to what might happen in the real world for such genotype directed therapy.

References


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