Author's response to reviews

Title: Rapid bronchodilatory effect of formoterol and salbutamol in acute asthma: A double-blind, randomized controlled trial.

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Version: 2 Date: 27 April 2011

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Sir,

Thank you for providing an opportunity to clarify the issues highlighted. The point-wise clarifications are as follows:

1. Ethics/consent: The research protocol was approved by the Ethics Committee of the All India Institute of Medical Sciences (Ref No: C/A-72/2.08.2008) (In the submission we wrote: ‘The study protocol was approved was by the Institute Ethics Committee’. The research was carried out in compliance with the Helsinki Declaration. The patients were enrolled after obtaining written informed consent from the parents. These aspects have been highlighted in the revised manuscript.

2. Advance of submission and inclusion of further citation: As suggested, we have included in our revised manuscript the systematic review by Welsh and Cates (2010), which was missed inadvertently- ‘In a systematic review conducted to assess the efficacy and safety of formoterol as reliever therapy in comparison to SABAs in adults and children with asthma, the authors reported that formoterol was similar to SABAs when used as a reliever, and showed a reduction in the number of exacerbations requiring a course of oral corticosteroids in adults (5). However, for children with asthma, there was insufficient information reported in the included trials to arrive at any conclusion on the safety or efficacy of formoterol as reliever (5).’. The published studies comparing formoterol and salbutamol in children are few, also highlighted in the Cochrane review. There are no published studies that have compared formoterol with salbutamol delivered by metered dose inhaler with a spacer in acute exacerbation of asthma in children. Our study shows that salbutamol or formoterol delivered by metered dose inhaler with spacer in children between 5-15 years of age with mild acute exacerbation of asthma have similar rapid onset of bronchodilator action. This finding would support the use of formoterol as a reliever medication. This approach may help avoid carrying two different MDIs (salbutamol and steroids with formoterol), which will improve patient compliance.

With best wishes
Rakesh