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Letter to the editor - serious asthma events with fluticasone plus salmeterol versus fluticasone alone

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To The Editor

Stempel et al [1] compared serious asthma events in Fluticasone-Salmeterol with Fluticasone alone in AUSTRI trial. Sum up of patients of four subgroups in severe asthma exacerbation (SAEx), 480 patients out of 5834 in fluticasone-salmeterol and 597 out of 5845 in fluticasone group had SAEx. The hazard ratio for severe asthma exacerbations in fluticasone-salmeterol group versus fluticasone alone is 0.78 (95% CI, 0.69 to 0.89; P = 0.0002) as per ITT and 0.76 (95% CI, 0.67 to 0.87;P = 0.0002) as per PP analysis, although non-inferiority was establish with regard to composite safety endpoints (HR = 1.03 (95% confidence interval [CI], 0.64 to 1.66), Non-inferiority margin as 2). Stempel et al [1] states that there is no difference with regard to composite safety endpoints as per race. But if we compare the composite safety end point (hospitalization, endotracheal intubation, or death) or serious asthma related event (SARE) in black patients versus white patients in Salmeterol-fluticasone group, the hazard ratio is 2.41 (95% CI, 1.13 to 5.14; P = 0.02), statistically significant. The hazard ratio for SARE in blacks' patients in fluticasone group is 1.80 (95% CI, 0.80 to 4.04; P = 0.15) versus white. The hazard ratio for SARE in black versus white patients in both treatment groups combined is 2.09 (95% CI, 1.21 to 3.63; P = 0.009) (Figure 1). Thus, an additional finding of this study is that the risk of serious asthma related events is 109% higher among black patients as compared to white [2,3]. These finding are similar to the findings by The Asthma and Allergy foundation of America, which states that overall black to white asthma mortality ratio for the nation is 3.0 [2].

This may imply that we should be cautious while using combination of salmeterol-fluticasone while we can safely use fluticasone alone in blacks, as this study have established non-inferiority of both the therapies. However, meta-analysis is needed to further strengthen the evidence .



Figure 1. Forest plot of composite safety end points (serious asthma related events) in black versus white patients in both treatment groups

Author's contribution

Author SS, RK have written, edited and approved the final manuscript/correspondence.

Declaration of interest

Author SS, RK declare that they have no conflict of interest. Dr. Kaur has nothing to disclose. Dr. Singh has nothing to disclose.

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Not Applicable.

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