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Title: Effects of Arg16Gly polymorphism in ADRB2 gene on responses to salmeterol or montelukast added to inhaled corticosteroids in Japanese asthmatic subjects

Dr. Satoshi 17742 Konno satkonno@med.hokudai.ac.jp MD [1], Dr. Hironi 17743 Makita hiro@hokkaido.med.or.jp MD [1], Dr. Nobuyuki 17744 Hizawa nhizawa@md.tsukuba.ac.jp MD [2], Dr. Kaoruko 17745 Shimizu okaoru@med.hokudai.ac.jp MD [1], Dr. Fumio 17746 Kokubu fkokubu@med.showa-u.ac.jp MD [3], Dr. Takefumi 17747 Saito saito@seiransou.hosp.go.jp MD [4], Dr. Takeo 17748 Endo t.endo.d@mn.hosp.go.jp MD [5], Dr. Hiroki 17760 Ninomiya hiro6047@gmail.com MD [6], Dr. Hiroaki 17749 Iijima hiijima-alg@umin.ac.jp MD [7], Dr. Norihiro 17752 Kaneko nkaneko@kameda.jp MD [8] and Dr. Masaharu 17753 Nishimura ma-nishi@med.hokudai.ac.jp MD [1]. [1] First Department of Medicine, Hokkaido University, Sapporo, Japan ; [2] Department of Pulmonary Medicine, Tsukuba University, Tsukuba, Japan ; [4] Department of Respiratory Medicine, Showa University Fujigaoka Hospital, Yokohama, Japan ; [5] Department of Respiratory Medicine, Ibaragihigashi National Hospital, Toukai, Japan ; [6] Department of Respiratory Medicine, Mito Medical Center, Higashiibaragi, Japan ; [7] Department of Respiratory Medicine, Kobari General Hospital, Noda, Japan ; [8] Department of Respiratory Medicine, Tsukuba Medical Center, Tsukuba, Japan and [9] Department of Respiratory Medicine, Kameda Medical Center, Kamogawa, Japan .

Body: Rationale: Long-acting b2-agonists (LABA) and leukotriene receptor antagonists (LTRA) are two recommended agents to add to inhaled corticosteroids (ICS) in asthma patients not adequately controlled by ICS alone. Conflict studies exist on whether the Arg16Gly genotype in b2-adrenergic receptor (ADRB2) gene may influence the bronchodilator effect of b2-agonists, and some indicate that subjects with Arg/Arg show deterioration in pulmonary function with long-term LABA treatment. Objective: We hypothesized that the Arg16Gly genotype might determine the differential response to either LABA (salmeterol, Sal) or LTRA (montelukast, Mon) when added to ICS in patients with asthma. Methods: This study was a randomized, cross-over design and 62 mild to moderate asthma patients (26 patients with Arg/Arg, 36 patients with Gly/Gly) were enrolled. The primary endpoint was a difference of the change in the morning PEF at 16 weeks [ΔPEF (Sal) – ΔPEF (Mon)] between the two genotypes. Results and Conclusion: The mean difference in [ΔPEF (Sal) – ΔPEF (Mon)] was 16 ± 50 (SD) in patients with Arg/Arg, and 16 ± 41(SD) in patients with Gly/Gly ($P>0.05$). This result suggests that the Arg16Gly genotype does not influence the preferential bronchodilator effect of Sal or Mon in mild to moderate persistent asthma patients, at least, in 16 weeks follow-up.