第173回東京医科大学医学会総会

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The effects and safety of standard therapy for COPD patients who were not previously receiving maintenance treatment

(呼吸器内科学)

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UPLIFT trial showed that tiotropium significantly improved lung function, health-related quality of life and reduced exacerbations of COPD, but had no effect on the primary end-point of rate of decline in FEV1 in the full cohort. Several secondary reports have documented that tiotropium reduced the rate of decline in pre and post-bronchodilator FEV1 in patients who were not previously receiving any maintenance treatments. The Japanese cohort in sub-analysis of UPLIFT showed that the rate of decline in FEV1 in Japanese patients treated with tiotropium was a comparable rate of decline in FEV1 in healthy subjects without COPD (29 mL \pm 44 per year). In this cohort, over 95% patients experienced medication for COPD. Based on this knowledge, we investigated the efficacy and safety of standard pharmacological agents for Japanese patients with COPD who were not previously receiving any maintenance treatment.

[Methods] Key inclusion criteria were age >40 years, smoking history of >10 pack-years, post-bronchodilator FEV1/FVC <70% and patients who were not previously receiving any maintenance treatment. Key exclusion criteria were COPD exacerbations or respiratory infections within 4 weeks before screening, a history of asthma, prior pulmonary resection or use of supplemental oxygen for >12 h/day. Eligible patients were randomized to receive standard therapy in accordance with GOLD guideline. Spirometry, COPD assessment test (CAT) as QOL, and Physical functioning scale of 10 (PF 10) were performed every 2 month for 1 year.

[Results and Discussion] 49 patients were enrolled in this study. Change in pre- and post bronchodilator FEV1 was 121 ml before maintenance treatment. Annual rate of decline in FEV1 was 20 ml/year which was a comparable rate of decline of Japanese patients in UPLIFT. CAT score improved, especially score in domain of cough and dyspnea showed statistically significant improvement. PF10 score also improved. The proportion of patients with an exacerbation was 0.05/patient/year, which was much lower than data in Japanese patients of UPLIFT (0.37/patient/year), suggesting that this group was unsusceptible to exacerbation. Adverse events was 43%, which accounted for no serious events like a dry mouth.

[Conclusion] In Japanese patients with COPD who who are not on maintenance therapy, standard treatment in accordance with GOLD recommendation is associated with significant benefits in disease progression.

P1-11.

食後高血糖に対するビルダグリプチンとミグリ トール・ミチグリニドの併用効果

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【背景・目的】 HbA1c が同レベルであれば血糖変 動が小さいほど血管内皮細胞や神経細胞への影響が 少ないなど、糖尿病に伴う大血管症や細小血管症に 食後高血糖が密接に関係することが明らかにされ、 治療においてもその是正の重要性が強調されてい る。

以前より食後高血糖を選択的に治療する薬剤とし て α グルコシダーゼ阻害薬やグリニド薬が用いら れ、昨今では DPP-4 阻害薬などのインクレチン関 連薬が食後高血糖を改善すると期待されており、こ の 3 剤の併用も可能となってきている。食後高血糖 に対するビルダグリプチンとミグリトール・ミチグ リニドの併用効果を検討した。

【方法】 対象は、演者の外来を受診した未加療の2 型糖尿病患者40名のうち、28週間の観察が継続で