

Executive Summary

To understand the current status of the use of inhaled bronchodilator and inhaled steroids, which are the core treatment for patients with chronic airway diseases, and to provide important clinical information, the study was conducted as follows: 1) the current status of the prescription for and the use of inhaled bronchodilator and inhaled steroids in the country was examined using the Health Insurance Review & Assessment Service's claims data, and the incidence of diseases depending on the drug use was compared. 2) Clinical changes such as disturbed urination, frequency of dry mouth, and depression/anxiety after the use of inhaled drug treatment, which are difficult to find out from the analysis of the Health Insurance Review & Assessment Service's claims data, were examined by conducting the survey on patients.

I. Review of the current use

The analysis for current use by the Health Insurance Review & Assessment Service's health insurance claims data showed that the number of cases claimed between 2006 and 2010 for inhaled bronchodilator and inhaled steroids at the Health Insurance Review & Assessment Service was 33,276,366, the number of patients was 2,651,982, and the number of new patients was 1,099,536. In the claimed statements, the frequency for the prescription for 0~9 years patients was the highest, but the 60s~70s were mostly prescribed in patients and new patients. Asthma was the most frequent cause for prescription in both patients and new patients. For drug effect groups of prescribed drugs, long-acting beta-2 agonist/inhaled steroids(LABA/ICS) was the mostly prescribed in patients and also in new patients, with similar tendency by year.

For medication adherence of inhalants, bronchiectasis was 4.30%, sequela

of tuberculosis 6.22%, COPD 4.07%, and asthma 1.63% in patients prescribed for over 70%(511 days); bronchiectasis 9.74%, sequela of tuberculosis 11.79%, COPD 8.64%, and asthma 4.27% in patients prescribed for over 50%(365 days), showing the lowest medication adherence in asthma, during the 2 years of follow-up period. Also, 79.95% of asthma patients changed their medication, which was the highest among 4 diseases, and also asthma patients were the highest as 47.13% in patients prescribed for over 70%(511 days) during the 2 years of follow-up observation. However, bronchiectasis patients were the highest as 62.47% in patients prescribed for over 50%(365 days).

2. Comparative effectiveness study

The case-control study within the cohort was performed to evaluate the relationship between the inhalant use and the incidence of lung cancer or laryngeal cancer. The results showed that the risk for lung cancer incidence in ICS users was 0.79 times lower compared to ICS non-users, and the risk for lung cancer incidence by the cumulative use of ICS had a dose-response relationship, and the risk for lung cancer incidence was decreased as the cumulative use was increased, with similar results in the subgroup analysis and the sensitivity analysis. The risk for laryngeal cancer incidence was also decreased in the ICS user group, but not statistically significant.

The results of the patient-control study for the evaluation of the relationship between the inhalant use and tuberculosis incidence within the cohort with the same study design showed that the risk for tuberculosis incidence was 1.23 times higher in ICS users compared to ICS non-users, and the risk for tuberculosis incidence by the cumulative use of ICS had a dose-response relationship, and the risk for tuberculosis incidence was increased as the cumulative use was increased, with similar results in the subgroup analysis and the sensitivity analysis but with some differences in ICS and the risk of tuberculosis incidence depending on the use of OCS.

In addition, the risk for hospitalization and emergency room visit due to the inhalant use and pneumonia in the case-crossover design showed that the use of ICS only during the control period between 60-30 days before the index date increased the risk for hospitalization and emergency room visit due to pneumonia by 1.73 times, but the combined use of ICS and LABA was rather decreased the risk by 0.63 times, with similar results during the control period between 390-360 days, 210-180 days, and 120-90 days before the index date, with similar results in various subgroup analyses and the sensitivity analysis.

3. Patients Survey

In the survey of new patients using inhalants, 90 patients were involved in the analysis. No urination disturbance was observed before and after the use of inhalants. The presence of dry mouth was increased in LAMA group from 5.27 before use to 10.46 after the 12-week use, but not changed in ICS/LABA group. The depression index was increased from 9.61 to 10.85 after the 12-week use of inhalants, and particularly the anxiety index was decreased from 4.28 to 4.22 in ICS/LABA and increased from 3.42 to 4.48 in LAMA group, but no significant difference was observed statistically in the changes between two groups.

Also, in the marginal model analysis, no significant differences were observed statistically in the changes of IPSS and HADS scores by time between ICS/LABA group and LAMA group after being corrected for age, gender, basal FEV1, BMI, and smoking. However, in case of dry mouth, no significant difference was observed statistically by time in ICS/LABA group, but increased 1.62 points a month in LAMA group.

This study used the Health Insurance Review & Assessment Service's claims data and thus had limitations in the analysis due to the lack of various clinical variables such as the presence of smoking and the results of

pulmonary function tests, which are important variables in patients who use inhalant; in the case-control study design, matched for COPD (J41–J44) to overcome such limitations.

Although inhaled bronchodilator and inhaled steroids are important and core drugs in the treatment of chronic airway diseases such as asthma and COPD, the current status of domestic drug use and the comparison of performance after drug use are not sufficiently available. Thus it is considered that the results of this study provide important clinical information to medical professionals and policy decision-makers.