

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: N/A

ACTIVE INGREDIENT: N/A

Study No: NIS-RTH-SYM-2008/1
BUDESONIDE/FORMOTEROL FOR MAINTENANCE AND RELIEVER THERAPY: A MEDICATION USE EVALUATION AMONG PERSISTENT ASTHMA PATIENTS IN GENERAL PRACTICE IN THAILAND

Developmental Phase: NIS

Study Completion Date: 25 Nov 2009

Date of Report: 05 Oct 2010

OBJECTIVES:

To determine the incidence of over-use and under-use of B/F for maintenance and reliever therapy in usual-care setting.

METHODS:

This study is a hospital-based cross-sectional, epidemiological survey and retrospective chart review, multi-center study. A total sample size of 792 was selected consecutively from 23 hospitals across Thailand. Patients with persistent asthma and receiving B/F for maintenance and reliever therapy for 3 months or longer were selected. We define the over-use as use more than 12 puffs per day. For under-use, it refers to use less than prescribed for more than 20% of days during the last 3 months. This study outcome was based on face-to-face interview with the patient by the researchers who are independent of the responsible physicians.

RESULTS:

Among a total of 792 patients, 73.5%, were females, 52.2±15.0 years of age, 89.4% were non-smokers. Duration living with asthma symptom ranged from 0.3 to 75.5 years, with a median of 10.3 years. At the most recent visit, almost all patients, 96.7%, were prescribed B/F with strength of 160/4.5. About two thirds, 68.5%, of patients were prescribed at a dose of 320 µg per day, followed by 640 µg per day prescription for 12.3%.

Of 792 patients which constituting 2,376 person-months of observations, there was only one patient who used more than 12 puffs per day for 3 days. The rate of over-use was

0.015 days per patient per year (95%CI: 0.003 to 0.044) without any adverse events. On the other hand, there were 223 (28.2%) patients who reported under-use, i.e., did not use or used less than prescribed for more than 20% of days. The total number of days with under-use was 4,235, hence the rate was 21.39 (95%CI: 20.75 to 22.04) days per patient per year. There were 175 patients who used B/F in addition as needed (22.2%).

Mean dose of budesonide used was 355.3 ± 154.9 (95% CI: 344.5 to 366.1) μg per day. The average dose of used as controller exclusively was 348.8 ± 153.1 (95% CI: 336.7 to 361.0) μg per day while dose of used as controller and reliever was 378.0 ± 159.6 (95% CI: 354.2 to 401.8) μg per day. Overall, the average dose of budesonide that was actually used was 6.0 μg per day lower than the prescribed dose significantly (95%CI: 1.4 to 11.5; p-value = 0.013).

There were 39 (3.8%) patients who had at least one hospital admissions as inpatient– 24 (3.0%) to IPD ward and 1 (0.2%) to ICU. These contributed a total of 42 occasions of the admissions. Thus the IPD admission rate was 0.21 per patient per year (95%CI: 0.15 to 0.29).

There were 22 (2.78%) patients who had at least one emergency room (ER) visits with a total of 35 occasions (ER visit rate = 0.18 per patient per year; 95%CI: 0.12 to 0.26). In other words, we would expect about 18 ER visits per 100 patients in a year.

Overall, there were a total of 97 hospital admissions of any types. Thus the rate of all hospital admissions due to asthma was 0.49 per patient per year (95%CI: 0.40 to 0.60). In other words, we would expect about 49 hospital admissions per 100 patients in a year.

The ACT score ranged from 8 to 25, with a median of 24. The mean ACT score was 22.5 (standard deviation = 3.0). Among a total of 792 subjects, 685 had the ACT score of 20 or above. Thus the percentage asthma of control based on ACT score was 86.5% (95% CI: 84.1% to 88.9%).

Patients who had a score of 25 that represents a complete controlled was 28.7%.

Of the 685 patients whose predicted PEF can be calculated, 548 (80.0%) had their predicted PEF greater than 80%. The 95%CI was 77.0% to 83.0%. Combining the PEF criteria to the ACT in determining asthma control, the percentage of control was 72.0% (95%CI: 68.6% to 73.3%).

Overall, percentage of hospitalizations were statistically higher in patients whose asthma were uncontrolled than that of whose asthma were controlled. That is, patient with at least one hospital admissions of any types was 26.17% in uncontrolled group whereas it was 2.77% in controlled group with the difference of 23.39% (95%CI: 14.98% to 31.81%, p-value < 0.001). The corresponding magnitude of difference of ER visits was 9.76% (95%CI: 3.71% to 15.80%, p-value < 0.001).

Hoarseness of voice was the most common side effects, 15.1%, followed by irritation of mouth and/or throat, 13.4%. The rate of having at least one side effect was 9.68 (95% CI: 8.47 to 11.02) per patient per year. The majority of patients, 91.2%, preferred combined drugs rather than single drugs.