AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: NIS
ACTIVE INGREDIENT: N/A

Study No: NCT01176656 **Study ID: CV/NIS-CUS-DUM-2010/1**
Study Title: Hypoglycemia: Physician and Patient Perspectives

Developmental Phase: NIS
Study Completion Date: 6/30/2011 (Database Lock)
Date of Report: 12/05/2011

OBJECTIVES: The purpose of this study was to assess the burden of hypoglycemia and identify unmet needs related to the management of hypoglycemia among type 2 diabetes mellitus (T2DM) patients on antidiabetic drugs (ADs) with and without use of insulin.

The specific patient-focused objectives for this project were to:

- Assess the overall prevalence of hypoglycemia among patients with T2DM treated with OADs and compare the proportion of patients reporting hypoglycemia symptoms who were on SU, insulin and other OADs;
- Examine the relationships between patients' experiences with hypoglycemia and their and health care utilization and associated costs.

The specific physician-focused objectives for this project were to:

- Examine physicians' awareness of and experiences with hypoglycemia among their T2DM patients and assess physicians' approach to discussing hypoglycemia with their patients;
- explore the relationship between hypoglycemia and physicians' treatment perceptions and decisions; and
- examine physicians' perceptions of the relationships between patients' experiences with hypoglycemia and their treatment adherence and modifications, overall glycemic control, and health care resources utilization.

METHODS:

The current study was an observational research study that combined patient-reported and physician-reported data collected through mail surveys and administrative claims data (medical data, pharmacy data, and enrollment information). The study sample included adult commercial enrollees with T2DM identified in the administrative claims data from patients enrolled in a large geographically diverse managed healthcare plan in the United States during a 12-month time period and the physicians associated with their T2DM management. A central institutional review board (IRB) approved the study.

For the patient survey portion of the study, a sample of 3,999 patients was contacted directly by mail to participate. Patients were asked to provide consent by signing and returning informed consent forms. For the physician survey portion of the study, a sample of 2,000 physicians was contacted directly by mail to participate in a one-time survey. Patients were observed in the claims data for the 12-month period prior to their survey date to assess health care resource utilization and treatment patterns.

Results of the patient survey were merged with claims data for analysis. Descriptive and multivariate statistical methodologies were used. Data on outcome measures were analyzed stratified by hypoglycemia categories: confirmed hypoglycemia, unconfirmed hypoglycemia, and no hypoglycemia. Bivariate comparisons of demographic characteristics and outcome measures, including claims-based measures, were performed using appropriate tests (e.g., t-test, Mann Whitney-U test, or chi-square test) based on the distribution of the measure. Multivariate analyses of study endpoints were conducted using appropriate methodologies based on the distribution of the measure, the comparison selected for analysis, and modeling assumptions and requirements. Multinomial logistic regression was conducted on determinants of patient-reported hypoglycemia.

RESULTS:

A total of 813 patients responded to the mail survey (24% response rate). The average age of responders was 57 years old. There were more males than females in the study (58% vs. 42%). The racial distribution of the sample was 74% white, 17% African-American and 9% other race designation.

A total of 395 physicians responded to the mail survey (21% response rate): About half (48%) were primary care physicians (PCPs) and half (52%) were endocrinologists (ENDOs). The majority was between the ages of 35-64 years (85%) and was male (71%). Nearly 50% reported practicing medicine for 20 or more years; 40% practiced in an urban setting and 52% practiced in a suburban setting. ENDOs treated more than twice as many patients with T2DM as PCPs during the past 30 days.

Key Results

Patient-focused results:

- Patient-reported rates of hypoglycemia are three times higher than claims-based measure of hypoglycemia (28% vs. 9%).
- There was a gradation of the experience of hypoglycemia symptoms: the highest percentage of patients reporting any symptom was for patients treated with insulin (83%), followed by those treated with SU without insulin (70%), and followed by those treated with other ADs without insulin (56%).

- Patients with confirmed hypoglycemia had higher mean all-cause and diabetes-related (as measured by primary diagnosis code) physician office visits than did patients with unconfirmed or no hypoglycemia.
- Patients with confirmed hypoglycemia had a greater mean (SD) number of diabetes-related ambulatory visits, as well as a 19% greater risk for disease-related ambulatory visits than did patients with unconfirmed or no hypoglycemia.
- Mean all-cause pharmacy costs were significantly higher for confirmed hypoglycemia compared with unconfirmed and no hypoglycemia. No significant differences were found for all-cause medical costs.
- Diabetes-related costs were significantly higher for the confirmed hypoglycemia cohort compared to the unconfirmed and no hypoglycemia cohorts for physician office visits (difference of $77 and $116, respectively), pharmacy costs (difference of $1,356 and $1,510, respectively) and for total health care costs compared to the no hypoglycemia cohort (difference of $2,282) .
- Confirmed hypoglycemia had an increased cost ratio of 71% ($p<0.001$) for diabetes-related total health care costs compared to no hypoglycemia.
- Mean diabetes-related outpatient facility costs for the confirmed hypoglycemia and the unconfirmed hypoglycemia cohorts were higher than for the no hypoglycemia cohort (differences of $723 and $585, respectively). There were no differences among the hypoglycemia cohorts for diabetes-related emergency room costs, inpatient costs or total medical costs.

Physician-focused results:

- ENDOs were more likely to agree overall that their patients experienced hypoglycemia symptoms and that hypoglycemia was a problem for patients treated with ADs than were the PCPs.
- Both ENDOs and PCPs reported that they “always” or “often” discuss the importance of adherence to treatment, and the reasons, symptoms, prevention, treatment, and monitoring of hypoglycemia with their patients.
- Both ENDOs and PCPs agreed with the statements that sulfonylureas and insulin were associated with hypoglycemia. They disagreed with the statements that metformin, thiazolidinediones, alpha-glucosidase inhibitors, DPP-4 inhibitors and GLP-1 and amylin analogues were associated with hypoglycemia. ENDOs were more likely than PCPs to agree that meglitinides were associated with hypoglycemia.
- Both ENDOs and PCPs thought that ease of use of a medication, the ability to attain glycemic control, the level of routine physical activity, concomitant medications, the patient’s description of his/her hypoglycemia symptoms, and the impact of hypoglycemic symptoms on activities of daily living were important when making treatment decisions.
- Approximately 72% of physicians felt that hypoglycemia impacted patients’ antidiabetic medication adherence.

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