PB86

THE POTENTIAL CARDIOVASCULAR RISK OF ROSIGLITAZONE COMPARING TO OTHER ANTI-DIABETES AGENTS: A RETROSPECTIVE DESCRIPTIVE STUDY

Dengy, Ting J., Lin AC

University of Cincinnati College of Pharmacy, Cincinnati, OH, USA

OBJECTIVES: To compare the cardiovascular risk around the cardiovascular risk caused by rosiglitazone continues, as the results from recent pharmacoeconomic studies were believed inconclusive. The objective of this study is to do a descriptive study on the adverse events, especially cardiovascular events caused by rosiglitazone and other commonly used anti-diabetes agents. METHODS: FDA adverse event reporting system (FAERS) database was used for data analysis; reports were drawn from 1997 to 2011. Study drugs include rosiglitazone, pioglitazone, metformin, glipizide and glimepiride. Adverse events during time were calculated to see the trend. Frequency of adverse events described and stratified by age and gender. Different outcomes like the cardiovascular events, death and hospitalization associated with each study drug were evaluated. RESULTS: Over 200,000 reports (200,000-500,000) were received and not very much during years, except that rosiglitazone has a sharply increase from 2008 and decreased in 2011, in accordance with the 2007 meta-analysis published. Adverse events of different drugs differ in gender: there are 10% more adverse events in men compared to women. 14% more of rosiglitazone in male than female while metformin cause 8% more in female than male. Rosiglitazone has significantly more deaths (5588) and hospitalizations (28387) comparing to other four drugs (average 2225 death and 11521 hospitalization), and it also has more cardiovascular events (36.37%) than other four drugs (average 11.52%). CONCLUSIONS: Rosiglitazone seems to have more severe adverse events, especially cardiovascular events comparing to other four antidiabetic drugs.

PB7

RATE OF ANAPHYLAXIS ASSOCIATED WITH INTRAMUSCULAR TESTOSTERONE INJECTIONS

Mc L1, Summer KH2, Camper SB, Shusterman NH1

1Endo Pharmaceuticals Inc., Malvern, PA, USA; 2West Chester, PA, USA

OBJECTIVES: Intramuscular (IM) testosterone injections have been available since 1953 but significant immediate adverse reactions have not been well documented. The objective was to estimate the rate of anaphylaxis associated with IM testosterone injections. METHODS: This retrospective analysis utilized a large commercial claims database of a single consumer health plan between and 2007-2011. Adverse event and anaphylaxis were classified as “likely, probably, possible” based on the clinical review of patient’s medical history, treatment for anaphylaxis and existence of confounding diagnoses. The outcomes were the number of patients who received an IM testosterone injection(s) between 2007 and 2011. Anaphylaxis cases were selected based on the occurrence of anaphylaxis on the same day of the testosterone injection. The relationship between testosterone injection(s) between 2007 and 2011. Anaphylaxis cases were selected for analysis. RESULTS: Between 2007 and 2011, 989,778 IM testosterone injection were identified for a total of 120,402 males (mean age: 49.1 years). A total of 232 patients had at least one anaphylaxis claim within 365 days of receiving an IM testosterone injection. Among 40 same-day anaphylaxis cases (39 patients), there were 12 cases (12 patients) with anaphylaxis classified as “likely”, “probably”, “possible” in comparison to 10 patients, or 1.5 cases per 10,000 patient-years. There were 17 cases in 10,000 patients classified as “likely, probably, possible”, which represent a rate of 1.0 patient per 10,000 patients, or 1.5 cases per 10,000 patient-years. There were 17 cases (17 patients) with anaphylaxis classified as “likely” only, “probable” only, and “possible” only, in comparison to 10 patients, or 1.0 patient per 10,000 patients, or 1.5 cases per 10,000 patient-years. CONCLUSIONS: The preliminary analysis reveals that odds of α-HHV reactivation is approximately two times higher for the individuals with thyroid disorders. And, thyroid disorders are significantly associated with higher prevalence of α-HHV.

PB81

COMPOSITE QUALITY MEASURE (CQM) ATTAINMENT IN OVERWEIGHT/OBESE PATIENTS WITH TYPE 2 DIABETES MELLITUS TREATED WITH CANAGLIFLOZIN 300 MG (CAN) OR SITAGLIPTIN 100 MG (STA)

Taliero C1, Guerci G2, Rupnow MF3

1Janssen Scientific Affairs, LLC, Raritan, NJ, USA; 2Janssen Research and Development, Raritan, NJ, USA

OBJECTIVES: Public and private US payers use CQM to assess the quality of diabetes care and to incentivize improvement in care and associated outcomes. Examples of payers using CQMs include the Medicare Shared Savings Program (MSSP) and HealthPartners (HP). This review focused assessed CQM attainment with CAN and STA and the CQMs included in the MSSP analytic framework. Methods: The study used a retrospective cohort study examining the demographics of patients diagnosed with type 2 diabetes mellitus (T2DM) in a large commercial claims database and was similar between the two databases. The unique patients included in the sample will be identified with at least a medical claim for Thyroid disorder and an α-HHV diagnosis during the study period. Statistical analyses will be done using 2x2 contingency table developed. RESULTS: The preliminary analysis reveals that odds of α-HHV reactivation is approximately two times higher for the individuals with thyroid disorders. And, thyroid disorders are significantly associated with higher prevalence of α-HHV.

PB12

CLINICAL EFFECTIVENESS OF SURGICAL THERAPIES, RADIOTHERAPY AND MEDICAL INTERVENTIONS IN CUSHING’S DISEASE: A SYSTEMATIC LITERATURE REVIEW

Shahmoon V1, Rousseau G1, Koch C2, Hurry M1

1University of Montreal, Montreal, QC, Canada; 2NovaUCare Pharmaceuticals Canada Inc., Dorval, QC, Canada

OBJECTIVES: The objective was to examine the evidence on the efficacy of current treatments in patients with Cushing’s disease (CD) to support health care decision-making. METHODS: A systematic literature search using predefined strategy was performed. We included studies that used a randomised controlled trials that compared surgical, medical and/ or radiation therapy to conservative approaches of care. RESULTS: For recurrent/persistent CD (n=20/22), treatment was similar between the groups, the odds ratio was 1.27 (95% CI 0.58-2.81) better attenuation. For the MSSP CQM HbA1c-<8%,BP-140/90mmHg;LDL-C-100mg/dL; CAN demonstrated 6% (95% CI 1.4,11.9 and OR 1.58, 95% CI 1.1,2.08) better attenuation. Hypoglycemia rates for each group were similar. CAN was associated with higher rates of genetic myelomeningocele and advanced outcomes related to somatic disorders, but with few study discontinuations. CONCLUSIONS: Compared to SITA 100, CAN 300 mg treatment was associated with better CQM attainment in obese/overweight patients with T2DM. This information may inform payers on the comparative effectiveness of antihyperglycemic agents on attainment of diabetes CQMs which include glycemic, blood pressure, and lipid endpoints.

PB85

CHRONIC ILLNESS WITH COMPLEXITY: A MEDICARE ADVANTAGE POPULATION STUDY

Bhatkhachir V1, Pan Y1, Sambamourthi U1

1West Virginia University, Morgantown, WV, USA; 2West Virginia University School of Pharmacy, Morgantown, WV, USA

OBJECTIVES: To assess clinical outcomes among individuals having chronic illness with complexity (CIC) defined as ≥2 cases of type 2 diabetes mellitus (T2DM) and Parkinson’s disease (PD). METHODS: This study used a retrospective cohort design using Humana Medicare Advantage Part D claims database (2007-2011) and included elderly (age ≥ 65 years) Medicare beneficiaries with T2DM (identified by ICD-9-CM code of 250.xx or 250.xx) and PD (identified by ICD-9-CM code of 332.xx). Individuals with T2DM and PD (CIC) were matched to those with only T2DM and no PD (n=1,000) on sex, age, and diabetes complications severity index based on 8 on 1 GREEDY matching algorithm using propensity score. After propensity score matching there were 2,703 individuals with T2DM and PD and 8,109 with T2DM and no PD. Glycemic control outcomes (glycoHb<8%,<8.5%,<9.0%,<9.5%,<10.0%,<10.5%,<11.0%) and lipid control outcomes (LDL-C<100mg/dL) were identified. The Cochrane-Mantel-Haenzel method was used to compute HR and 95% CI. RESULTS: Individuals with both T2DM and PD were more likely to have clinically recommended glycemic and LDL-C control compared to those without CIC, suggesting that integrated systems may be beneficial to those with CIC.