5-070

Category: Drug-Use Evaluation

Title: Severe hypoglycemic events associated with non-guideline-concordant oral anti-diabetic drug treatments in patients with type 2 diabetes and moderate to severe chronic kidney disease: findings from a U.S. commercially-insured population

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Purpose: Purpose: To assess the rate of non-concordant use of oral anti-diabetic drug treatment (OAD) (according to National Kidney Foundation (NKF) guidelines) and its association with severe hypoglycemic events in patients with type 2 diabetes mellitus (T2DM) and moderate to severe chronic kidney disease (CKD).

Methods: Methods: Health administrative claims and laboratory findings from a US commercially-insured population were used to identify patients aged 18-64 who had two claims with associated ICD-9-CM code of T2DM (250.xx) and any stage 3-5 CKD from medical claims with associated ICD-9-CM code of 585.3-585.6 or dialysis procedures or lab findings with glomerular filtration rate less than 60 between 2005 and 2010. The date of first CKD indication was set as the index date. Patients were further selected if they filled at least 1 prescribed OAD during the 6 months following the index date (baseline period). OAD prescriptions were considered not guideline-concordant (non-GC) if they were were recommended to be avoided or did not comply with recommended dosage adjustment. Severe hypoglycemic events were identified based on associated diagnosis codes after the 6 months baseline period until loss of follow-up. A Cox proportional hazards regression model was used to assess the association between non-GC and severe hypoglycemic events, adjusting for patient demographic and clinical characteristics. The study was exempted from institutional review board review since data analyzed were encrypted and in compliance with the Health Insurance Portability and Accountability Act.

Results: Results: Of the final study sample (N=3,300; mean age: 56.0; 37.9% female; 83.2% stage 3 CKD), 58.3% were non-GC. When assessing individual OAD use for stage 3-5 CKD patients, based on kidney function or required adjustment of dosage according to NKF guidelines, the rate of non-GC use was 94.3% for glimepiride, 12.5% for acarbose, 28.6% for miglitol, 79.9% for metformin, 89.5% for nateglinide, and 40.1% for sitagliptin. After adjusting for patient characteristics, the non-GC patients were more likely to have severe hypoglycemic events (hazard ratio: 1.24, 95 % CI: 1.03-1.49) versus GC patients.

Conclusion: Conclusion: The findings suggested a higher risk of severe hypoglycemic events associated with non-GC OAD treatment among T2DM patients with moderate to severe CKD. Future studies are required to support the value of closely monitoring OAD treatments to ensure they are concordant with NKF guideline recommendations.