PROJECTED IMPACT ON CORONARY HEART DISEASE OF ADDING PROLONGED-RELEASE NICOTINIC ACID (NIASPAN®) TO STATIN TREATMENT IN EUROPEAN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: A recent Pan-European Survey highlighted a prevalence of low High Density Lipoprotein-cholesterol (HDL-c) <1.03 mmol/L in men and <1.29 mmol/L in women) in over 30% of patients diagnosed with dyslipidemia, irrespective of statin treatment. In order to help physicians focus their attention on this risk factor, a model was used to project clinical benefits on coronary heart disease (CHD) endpoints of raising HDL-c by Niaspan® to statin treatment in Type 2 Diabetes (T2D) patients. METHODS: A computer model simulated the clinical benefit of combination therapy statin + Niaspan®; the first sub-model (Monte-Carlo simulation) generated a cohort using patient characteristics from the Pan-European Survey (diabetic sub-group) and applied Niaspan® treatment effect (European SPC, 2g/day); the second sub-model (Markov) estimated the long-term clinical outcomes associated with patient’s lipid changes (Framingham risk equations). Simulations were run to capture 5, 10 years and patients’ lifetimes. RESULTS: In these patients, mean life expectancies of 19.42 years and 18.78 years were projected for the statin and statin + Niaspan® arms respectively (difference of 0.64 years). The addition of Niaspan® to statin treatment was associated with a lower cumulative incidence of CHD events than statin monotherapy at different time horizons leading to absolute risk reductions of 14.1% for myocardial infarction and 5.5% for CHD death. CONCLUSIONS: Due to its positive effect on HDL-c levels, the addition of Niaspan® to statin treatment was projected to reduce the cumulative incidence of CHD events compared to statin monotherapy in a European T2D patient population with persistently low HDL-c.

DISCONTINUED USE OF MYCOPHENOLATE MOFETIL AND GRAFT LOSS IN HEART TRANSPLANT RECIPIENTS

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OBJECTIVES: Changes in patterns of immunosuppression use have been associated with increased risk of adverse graft and patient survival outcomes. This study aimed to assess the relationship between discontinuing use of mycophenolate mofetil (MMF) on two-year graft loss and two-year patient death. METHODS: US claims data from commercial health plans for 396 patients receiving heart transplants (1995–2005) were linked to data from the Organ Procurement Transplant Network (OPTN). Transplant recipients were grouped into two: those who continued and those who discontinued (MMF DC) using MMF. MMF use was defined as having 21 pharmacy claim post-transplant for the medication. Discontinuation was defined as more than a 30 day gap in MMF coverage followed by no subsequent refills during the year following the initial MMF script. Cox proportional hazards analysis was used to estimate the risk of discontinuing MMF on graft loss and dying. RESULTS: Thirteen percent (N = 52) of the study population was in the MMF DC group. The majority of the population was between age 41 and 60 (57%), male (78%), transplanted between 1996–2000 (44%), and received a medication for a gastrointestinal condition during the year following their initial MMF script. Discontinuing use of MMF was associated with an increased risk of graft loss (Hazard Ratio [HR] = 3.43 p = 0.04) and an increased risk of death (HR = 2.79, p = 0.01) compared to continued MMF use during the year of follow-up. CONCLUSIONS: Disrupting the pattern of MMF use was related to a significant increase in the risk of graft loss and death during two years post-transplant in this heart transplant recipient population covered by commercial health plans. Future work should examine whether these findings extend to heart transplant recipients covered by other types of insurance and potential causes of therapy discontinuation.

outcome of thiazolidinedione use in discharged diabetic patients who were hospitalized for heart failure

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OBJECTIVES: Thiazolidinedione (TZD) was recommended not for patients with moderate and serious heart failure due to the adverse reaction of body fluid retention. Our study investigated the use of TZD by type 2 diabetic patients after they were discharged from hospitalizations for heart failure. METHODS: The cohort observation was based on claims database of Taiwan’s National Health Insurance (NHI) for 2002–2004. There were 4774 diabetic patients who were hospitalized due to heart failure during 2003: 379 TZD users and 4395 non-TZD users. A total of 2692 non-TZD users who used sulfonylurea after discharge were selected as the control group. Cox proportional hazard models were estimated to compared the outcomes of death and readmission to hospitals of TZD users and sulfonylurea users, one year after the time patients were discharged. RESULTS: There were 7.9% of diabetic patients who were hospitalized for heart failure and received TZD treatments. There was no significant difference on readmission over one year after discharge between the two groups. However, among those who used TZD or sulfonylurea less than 60 days, those who used TZD had lower HR of readmission than those who used sulfonylurea (HR 0.728, 95% CI 0.551–0.962). Overall, the HR for death among patients receiving TZD was significant lower than the control group sulfonylurea users (HR 0.092, 95% CI 0.022–0.380). CONCLUSIONS: Based on the precautions stated in TZD package inserts, 7.9% of type 2 diabetic patients with heart failure received potentially inappropriate prescriptions. Short term use of TZD significantly reduced hazards ratio in readmission, though long term use of both TZD and sulfonylurea showed no difference on readmission, and the use of TZD significantly reduced the hazard of death.