ASSOCIATION OF INADEQUATE METABOLIC CONTROL AND CO-MORBIDITIES AND HEALTH RESOURCE UTILIZATION IN PATIENTS WITH DIABETES MELLITUS IN A SPANISH POPULATION

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OBJECTIVES: To evaluate the influence of inadequate metabolic control (IC) in comorbidities and the utilization of resources of patients with diabetes mellitus attended at primary care setting (PCS) in daily practise. METHODS: A retrospective-multicenter population-based study was carried out, involving outpatient records (>30 years) managed at seven PCS during year 2006. NCEP-ATP III recommendations were followed, IC: HbA1c > 7%. The control-group was formed with patients without ICs. Main outcomes measures were comorbidity (hypertension, hypercholesterolemia, smoking, obesity, cardiovascular events [CVE], COPD, depression, microvascular complications, etc.), as determined by Charlson-index (severity), clinical parameters (BMI, total-cholesterol, LDL-cholesterol, HDL-cholesterol, glucose, triglycerides), resources utilization (specialist referrals, medical visits, drugs, diagnostic tests) and corresponding costs. Descriptive statistics, logistic regression model and analysis of covariance (ANCOVA) with Bonferroni correction were applied, using SPSSWIN v.12.0 and a statistical significance of p < 0.05.

RESULTS: A total of 5277 patients (age: 67.1 ± 12.0 years, women: 49.7%) were included in the analysis. 30.4% had IC (CI95%: 29.2–31.6%) and 25.0% (CI95%: 23.8–26.2%) suffered a CVE. Patients with IC: Charlson-index 1.2 ± 0.4 vs. 1.1 ± 0.3 and CVE 0.4 ± 0.7 vs. 0.3 ± 0.7, p < 0.0001. Logistic regression showed the association between IC and the existence of a stroke (OR = 1.3, CI95%: 1.1–1.6), smoking (OR = 1.4, CI95%: 1.2–1.6) and retinopathy (OR = 1.5, CI95%: 1.2–1.8), p < 0.001. Clinical parameters in patients with/without IC, respectively: BMI 30.5 ± 5.5 vs. 29.9 ± 4.9 kg/m2, glucose 176.4 ± 59.0 mg/dl vs. 128.1 ± 30.9 mg/dl, triglycerides 175.0 ± 150.4 vs. 143.2 ± 91.7, total-cholesterol 195.5 ± 44.2 vs. 189.4 ± 38.2, LDL-c 110.0 ± 72.0 vs. 106.8 ± 33.8 mg/dl (p < 0.002). Total cost/patient/year adjusted (age-sex, morbidity) was: €1612.18 (CI95%: €1490.48–1733.88) vs. €1937.49 (CI95%: €1829.53–2045.45), pharmaceutical cost represents a 21.5% (CI95%: 18.9–24.4%) and CVE 0.39—p < 0.01, -0.43—p = 0.02, -0.38—p = 0.03 vs. OCSEM: -0.48—p < 0.01, -0.72—p = 0.12, -0.31—p = 0.11) CONCLUSION: Our large national OCSEM results converge with 2 RCTs in regards to the cross-regimen difference of treatment effects. This may indicate a good external validity of 2 RCTs. OCSEM are larger sample methods that may have better external validity, but require a large sample size. Compared to PSM, MSM and DRM are less efficient, may require an even larger sample size.

LONG-TERM CLINICAL OUTCOMES OF INSULIN DETEMIR VERSUS NPH FOR TYPE 1 DIABETES PATIENTS IN SPAIN

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OBJECTIVES: To estimate the long-term clinical outcomes in type 1 diabetes patients treated with either insulin detemir (IDet) or neutral protamine Hagedorn (NPH) insulin based basal-bolus therapy in a Spanish setting. METHODS: A validated computer simulation model of type 1 diabetes (the CORE Diabetes Model) was used to make long-term projections of clinical outcomes based on patient characteristics (mean age 40.3 years, duration of diabetes 16.3 years, HbA1c 8.3%, BMI 25.2 kg,m–2) and treatment effects (HbA1c improvement of 0.13% points, a 4% decrease in hypoglycaemic events and lower body mass index of 0.21 kg,m–2 with IDet) from a fixed-effects meta-analysis of three clinical trials (n = 1555) where patients received either NPH or IDet as the basal component of therapy. Clinical outcomes were discounted at 3.5% per annum. RESULTS: IDet was projected to improve discounted life expectancy by approximately 0.082 years (14.42 ± 0.17 versus 14.33 ± 0.17 years) and quality-adjusted life expectancy by 0.173 quality-adjusted life years (QALY) (7.21 ± 0.09 versus 7.04 ± 0.08 QALYs) compared to NPH. The mean time to onset of any diabetes-related complication was delayed by 0.07 years in the IDet arm (1.11 versus 1.04 years) with the cumulative incidence (CI) of diabetes related complications over the patient lifetimes reduced. For example, the CI of end stage renal disease (ESRD) was 2.4% lower (18.3% versus 18.8%) with IDet versus NPH and, similarly, benefits were projected for proliferative diabetic retinopathy (4.4% lower, 21.7% versus 22.7%) and peripheral vascular disease (2.7% lower, 14.4% versus 14.8%). CONCLUSION: The use of IDet versus NPH was projected to lead to reduced complication costs over patient lifetimes, particularly for ESRD and retinopathy, due to improvements in glycaemic control. This is despite the survival paradox whereby IDet patients live longer than those receiving NPH and are therefore at a greater risk of complications.

VALIDATING THE EXTERNAL VALIDITY OF RANDOMIZED CONTROLLED TRAILS WITH OBSERVATIONAL STUDIES AND CAUSAL EFFECT METHODS (PROPENSITY SCORE, MARGINAL STRUCTURE MODEL AND DOUBLY ROBUST METHODS)

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OBJECTIVES: To validate the external validity of 2 randomized controlled trials (RCTs) through using large national observational studies that used electronic medical records and causal effect methods, such as propensity score (PSM), marginal structure model (MSM) and doubly robust methods (DRM).

METHODS: The results of 2 RCTs (n = 105 and 97; crossover at 16th weeks) were validated using national observational studies with causal estimation methods (OSCEM) studies (n = 4,519, in 4 post-baseline quarters). The common outcomes were the differences of treatment effect between 2 insulin regimens. The treatment effect was defined as the reduction of hemoglobin A1c (HbA1c) among patients with type 2 diabetes. The 2 insulin regimens were once-daily basal analog insulin (QDBAI)—glargine vs. twice-daily premixed analog insulin (BIDMAI)—ispro mix 75/25. The causal estimation methods include propensity score, marginal structural model and doubly robust methods.

RESULTS: The differences of HbA1c reductions between BIDMAI and QDBAI in 4 quarters estimated through 2 RCTs were similar to the differences estimated through 3 OSCEMs (RCTs: -0.39—p = 0.02, -0.38—p = 0.03 vs. OCSEM: -0.48—p < 0.01, -0.72—p = 0.12, -0.31—p = 0.11))

CONCLUSION: Our large national OCSEM results converge with 2 RCTs in regards to the cross-regimen difference of treatment effects. This may indicate a good external validity of 2 RCTs. OCSEM are larger sample methods that may have better external validity, but require a large sample size. Compared to PSM, MSM and DRM are less efficient, may require an even larger sample size.