PDB17

GLYCEMIC VARIABILITY AND COMPLICATIONS IN PATIENTS WITH DIABETES MELLITUS: EVIDENCE FROM A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: Large prospective clinical studies in both type 1 Diabetes Mellitus (T1DM) and type-2 diabetes mellitus (T2DM) have shown that high HbA1c levels is a strong predictor of diabetic complications. New data suggest that variability in glucose values, specifically excursions in postprandial hyperglycemia, may also play a significant role in the risk of microvascular and macrovascular complications. The aim of this review was to assess the published evidence for an association between glycemic variability and diabetic complications in patients with DM. **METHODS:** A systematic review of studies published in English between 1990-November 2008 was undertaken. Studies in patients with T1DM or T2DM reporting a) measures of glycemic variability; and b) its impact on the development or progression of diabetic complications were assessed. **RESULTS:** Eighteen studies were identified. Seven and 11 studies focused on T1DM and T2DM patients, respectively. Studies in patients with T1DM revealed that glucose variability has little impact on the development of diabetic complications. Only in two T1DM studies did glucose variability have a significant association with prevalent peripheral neuropathy and presence of nephropathy, but not with other complications. Among T2DM studies, a significant positive association between glucose variability and the development or progression of diabetic complications was reported in 10 of 11 studies. The risk of progression to diabetic retinopathy was significantly increased among patients in higher quartiles of glycemic variability (CV-FPG): 2nd quartile OR = 3.47 (95%CI:1.06–11.5); 3rd quartile OR = 3.66 (95%CI:1.12–12); and 4th quartile OR = 6.95 ((95%CI:2.1–22.4). Similarly, the risk of all cause and cardiovascular mortality was significantly higher among patients in the 2nd and 3rd tertiles of CV-FPG. **CONCLUSIONS:** This overview of the available evidence suggests that glucose variability may be an independent predictor of complications regardless of HbA1c levels in patients with T2DM. Better control of blood glucose excursions may reduce the risk of these complications.

DIABETES/ENDOCRINE DISORDERS – Cost Studies

PDB18

A BUDGET IMPACT MODEL (BIM) TO ASSESS THE IMPACT ON THE ITALIAN NATIONAL HEALTH SERVICE (INHS) BUDGET OF THE INTRODUCTION OF MIMPARA (CINACALCET) IN THE NEW INDICATION PRIMARY HYPERPARATIROIDISM (PHPT)

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OBJECTIVES: To evaluate the financial impact on the INHS following the introduction of cinacalcet for patients with intractable PHPT or in those whom parathyroidectomy (PTX) is contraindicated. **METHODS:** The number of patients eligible for cinacalcet was estimated by literature and local demographic information. The BIM simulates the impact of PHPT management in patients with or without cinacalcet. Resources to manage patients not receiving cinacalcet included drugs for treatment of secondary osteoporosis, visits and diagnostics and a second PTX for patients refractory to their first PTX. Resources to manage patients receiving cinacalcet included 60 mg/day cinacalcet and all of the above except the re-surgery. The total cost was calculated by applying the resources used, the INHS tariffs for visits, diagnostics and surgery and the reimbursed price for drugs. **RESULTS:** It was estimated that in the first three years following market introduction, just 113, 320 and 490 out of 1400 eligible patients with PHPT would be placed on cinacalcet therapy respectively. The baseline cost of PHPT management resulted in €794 per patient, per year (€256 for drugs, €314 for re-surgery, €224 for diagnostics). The introduction of cinacalcet resulted in a cost of €3698 per patient per year with cinacalcet costing €4380, partially offset by savings due to less other drugs (−€256), avoiding PTX (−€314) and less diagnostics (−€112). The total incremental annual budget increase due to addition of cinacalcet was €417,864, €1,183,332 and €1,811,978 in the first three years, respectively **CONCLUSIONS:** Because of the low prevalence of intractable PHPT, the incremental financial BI on the INHS following the introduction of cinacalcet would be very small and partially offset by savings from less health care resource use. Based on these calculations, the INHS granted reimbursement for cinacalcet in this new indication in 2008.

PDB19

ECONOMIC EVALUATION OF LONG TERM SOMATOSTATIN ANALOGS IN THE TREATMENT OF ACROMEGALY IN MEXICO: MONOTHERAPY VS SEQUENTIAL THERAPY

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OBJECTIVES: To compare cost and effectiveness between monotherapy with octreotide LAR® vs sequential therapy with lanreotide Autogel® and octreotide LAR® (long term somatostatin analogs) in the treatment of patients with acromegaly, from an institutional perspective, in the Mexican setting. **METHODS:** Cost-effectiveness analysis using a decision tree model that simulates the cost and efficacy of the treatment of acromegaly with long term somatostatin analogs: monotherapy with octreotide LAR® vs. sequential therapy with lanreotide Autogel® and octreotide LAR® or vice versa, for a temporary horizon of 18 months. The effectiveness measure was the percentage of patients achieving a reduction in IGF-1 and growth hormone levels, obtained from clinical trials published in international literature. Only direct medical costs were considered in the analysis. Costs were estimated using prices of 2008 and are expressed in US dollars (exchange rate of 11.14 pesos/ 1 US dollar). **RESULTS:** Octreotide LAR® monotherapy lead to 30% of patients achieving a reduction of IGF-1 and growth hormone to safe levels, whereas sequential therapy achieved 37.8% patients with hormone reduction to safe levels. The treatment with lanreotide Autogel®/octreotide LAR® showed the best average cost $24,792.3, per acromegalic patient treated, followed by the treatment with octreotide LAR®/ lanreotide Autogel® with a cost of $28,925.8 and finally octreotide LAR® monotherapy with a cost of $29,514.0. According to incremental analysis, the treatment with lanreotide Autogel®/ octreotide LAR® is the dominant alternative. Univariate sensitivity and probability analyses results show the same trend as the basic scenario. **CONCLUSIONS:** Lanreotide Autogel®/octreotide LAR® is the best cost-effective acromegaly treatment, from the institutional perspective in the Mexican context.

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COST EFFECTIVENESS ANALYSIS OF SWITCHING PATIENTS WITH POORLY CONTROLLED TYPE 2 DIABETES TO INSULIN DETEMIR FROM ORAL ANTIDIABETICS OR NPH IN THE CZECH SETTING; DATA FROM THE PREDICTIVE STUDY

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OBJECTIVES: The aim of this health economic analysis was to assess the cost-effectiveness of insulin detemir (IDet) + oral antidiabetics (OAD) versus OAD alone or neutral protamine Hagedorn (NPH) + OAD in patients with type 2 diabetes, based on the Czech sub-cohort type 2 patients of the large observational study PREDICTIVE. **METHODS:** A published and validated computer CORE Diabetes Model was used to project long-term economic and clinical outcomes in a cohort of type 2 diabetes patients treated with either IDet + OAD versus OAD alone or neutral NPH + OAD, in the Czech setting. Probabilities of complications, management costs adjustments (including complications and treatment costs) were derived from the Czech surveys from 2007. Future costs and clinical benefits were discounted at 3,5% per annum. **RESULTS:** IDet + OAD treatment was projected to improve life expectancy by approximately 0.53 versus OAD /0,26 years versus NPH + OAD (9,33/9,27 versus 8,80/9,01 years) and quality-adjusted life expectancy by 0.29/0,68 quality-adjusted life years (5,75/6,02 versus 5,46/5,34 QALYs). Treatment and complication costs associated with IDet treatment were higher over patient lifetimes than with OAD with difference 76 862 CZK (260 628 CZK/QALY) and lower than with NPH + OAD with difference −151 409 CZK (CZK/QALY dominant). **CONCLUSIONS:** CORE diabetes T2 patients sub-cohort simulation in 35 years perspective from PREDICTIVE study has demonstrated acceptable cost-effectiveness for patients with type 2 diabetes treated IDet+OAD. IDet + OAD treatment was projected to be associated with improvements in life expectancy, QALYs and acceptable or cost saving compared to OAD/ NPH +OAD. Sensitivity analyses show cost-effectiveness result to be robust.

PDB21

ECONOMIC EVALUATION OF RAPID-ACTING INSULIN ANALOGUES FOR THE TREATMENT OF PATIENTS WITH TYPE 1 AND TYPE 2 DIABETES MELLITUS IN CANADA

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OBJECTIVES: To estimate the cost-effectiveness of rapid-acting insulin analogues (RAIA) compared to regular human insulin (HI), for the treatment of diabetes mellitus (DM). This information may assist policy makers in making informed decisions on reimbursement of RAIAs. **METHODS:** An economic evaluation, from the perspective of a third-party provincial payer, was conducted using the Center for Outcomes Research (CORE) Diabetes Model (CDM). Clinical outcomes (e.g., A1c and hypoglycaemia) were derived from recent meta-analyses. Costs and utilities, both discounted at 5%, were obtained from published sources. Sensitivity analyses were performed to test the robustness of results. **RESULTS:** Type 1 DM (T1DM) – insulin aspart was more effective (0.055 quality-adjusted life years (QALYs)) and less costly (−$620) than regular HI. The incremental cost-utility ratio (ICUR) for insulin lispro relative to regular HI was $28,996 per QALY gained (difference (Δ) in cost, $182; Δ QALYs, 0.006). Type 2 DM (T2DM) – the ICUR for insulin aspart compared to regular HI, was $22,488 per QALY gained (Δ cost, $333; Δ QALYs, 0.015). The ICUR for insulin lispro, relative to regular HI, was $130,865 per QALY gained (Δ cost, $784; ΔQALYs, 0.006). Results were sensitive to variations of parameters in sensitivity analyses. **CONCLUSIONS:** Compared with regular HI, the use of RAIAs for the treatment of DM was associated with relatively low ICURs, with the exception of insulin lispro in patients with Type 2 DM, which was associated with a relatively high ICUR.