

**CV4**

**BENEFIT/RISK OF IRBESARTAN/HYDROCHLOROTHIAZIDE AS FIRST-LINE TREATMENT OF SEVERE HYPERTENSION**

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**OBJECTIVES:** Although guidelines recommend first-line combination therapy for patients with severe hypertension, no quantitative benefit/risk estimate has been provided. The objective of this study was to estimate these potential long-term benefits and risks based on results of a registrational clinical program.

**METHODS:** Results from a clinical study in severe hypertension (diastolic blood pressure \( \geq 110 \text{ mmHg} \)) were used to project benefits and risks of irbesartan/hydrochlorothiazide (I/H) vs. irbesartan monotherapy (I). In the randomized, controlled, double-blind, 7-week trial (\( n = 695 \)), initial I/H reduced exposure to severe blood pressure (BP) levels (\( p = 0.0003 \)) and provided an additional BP reduction of approximately 10/5 mmHg (systolic/diastolic) compared to I (\( p < 0.0001 \) for each parameter) with similar safety. Benefit was extrapolated by using cardiovascular risks described in World Health Organization Guidelines. The BP difference between I/H and I was applied conservatively to a time frame of 0.1 to 0.8 years, as physicians in actual practice may add adjunctive therapy after the initial prescription. The potential for serious adverse events from the use of I/H were estimated based on post-marketing surveillance data (10 million patient years of exposure to I/H) and literature review.

**RESULTS:** A population of 100,000 patients with severe hypertension is at risk for between 2,500 and 10,000 cardiovascular events in one year. Initial treatment with I/H instead of I is projected to prevent between 100 and 1,000 events in one year. No signal of potentially serious adverse events exists for I/H compared to I in post-marketing data, but an estimate of between 0 to 3 such events may be considered.

**CONCLUSION:** The estimated benefit/risk of first-line I/H is highly favorable, even when applied to a short time horizon. This is because cardiovascular risk is the greatest issue for the patient with severe hypertension. Earlier and more extensive use of combination therapy can improve public health.

**PODIUM SESSION I: ECONOMICS OF DIABETES**

**ED1**

**COST-EFFECTIVENESS OF INSULIN DETEMIR VERSUS NPH FOR TYPE 1 DIABETES PATIENTS IN A GERMAN SETTING. A MODELING EVALUATION BASED UPON RESULTS FROM A META-ANALYSIS**

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**OBJECTIVES:** A fixed-effects (weighted average) meta-analysis of three clinical trials showed the short-term therapy benefits of treating type 1 diabetic patients (mean age 40.3 years, duration of diabetes 16.3 years, HbA1c 8.3%, BMI 25.2 kg.m-2) with insulin detemir (IDet) versus neutral protamine Hagedorn (NPH) insulin as the basal component of basal-bolus therapy when used in combination with either insulin aspart (IAsp) or human soluble insulin (HSI). **METHODS:** A published validated diabetes model was used to estimate the long-term cumulative incidence of complications, life expectancy (LE), quality-adjusted life expectancy (QALE) and lifetime costs for IDet versus NPH regimens. The short-term treatment effects (0.13% points lower HbA1c, a 4% decrease in hypoglycaemic events and lower body mass index 0.21 kg.m-2) observed in the meta-analyses were projected using progression data derived from landmark clinical and epidemiological studies. The costs of treating complications in the German setting were taken from published sources and total direct costs (complications + treatment costs) for each arm were projected over patient lifetimes. Both costs and clinical outcomes were discounted at 5% annually.

**RESULTS:** The IDet arm was associated with an increase in life expectancy, compared to NPH, of 0.052 years (12.270 ± 0.130 versus 12.218 ± 0.121 years) with a resulting gain in QALE of 0.144 quality-adjusted life years (QALYs) (6.23 ± 0.07 versus 6.09 ± 0.06 QALYs) due to a reduction in diabetes-related complications. Increased treatment costs for IDet resulted in greater total lifetime costs per patient than with NPH (€91,960 ± 2,533 versus €89,367 ± 2,183, difference €2,593), leading to an incremental cost-effectiveness ratio of €18,070 per QALY gained.

**CONCLUSION:** Short-term improvements seen with IDet versus NPH in basal-bolus therapy were projected to show improvements in both life expectancy and quality-adjusted life expectancy with a cost-effectiveness ratio which fell well within the range usually considered to represent value for money (<€50,000 per QALY gained).

**ED2**

**LONG-TERM COST UTILITY ANALYSIS OF INSULIN ASPART (NOVORAPID®) VERSUS HUMAN SOLUBLE INSULIN IN TYPE 2 DIABETES PATIENTS IN THE GERMAN SETTING**

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**OBJECTIVES:** The aim of this analysis was to evaluate the cost-utility of switching type 2 diabetes patients receiving human soluble insulin (HSI) to rapid-acting insulin aspart (IAsp, NovoRapid), with or without oral hypoglycemic agents, in the German setting. **METHODS:** The CORE Diabetes Model, a published and validated computer simulation model, was used to project long-term clinical and economic outcomes associated with IAsp and HSI treatment effects. The model is based on 15 semi-Markov sub-models representing the most important acute and chronic diabetes-related complications including eye, renal