were randomized to either twice daily exenatide (N = 228) or once daily glargine (N = 227) during the 26-week, non-inferiority trial. The Vitality Scale of the Short Form 36, The Diabetes Symptom Checklist—Revised, The EuroQol instrument (EQ-5D), The Treatment Flexibility Scale, and The Diabetes Treatment Satisfaction Questionnaire (DTSQ) were administered at baseline and endpoint. Change from baseline to endpoint was compared within each treatment, and then between treatment groups with analysis of covariance models, controlling for country and baseline scores. **RESULTS:** At endpoint, exenatide and glargine achieved similar HbA1c reductions. In each patient reported outcome instrument, both treatment groups improved from baseline to endpoint; however no statistically significant differences were observed between the treatment groups. Because exenatide was associated with a higher incidence of nausea, the impact of treatment satisfaction, as measured by the DTSQ, was assessed for those exenatide patients who experienced nausea during the trial (n = 126). These patients demonstrated improvement from baseline to endpoint as well. **CONCLUSIONS:** Both injectable medications significantly improved the quality of life when added to pre-existing oral therapy. Exenatide, injected twice daily, was associated with an elevated incidence of nausea. However, despite the addition of an injection requirement and side effect of nausea, treatment satisfaction in exenitide group was comparable to that of the glargine group.

PDB6

REDUCTION IN DIABETES DRUGS USE AND DRUG COSTS IN OBESE PEOPLE TREATED WITH ORLISTAT

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OBJECTIVE: In addition to weight reduction, there may be other benefits of obesity treatment including improved insulin sensitivity. The purpose of this study was to characterise concomitant diabetes drug use and the related costs in diabetic patients treated with orlistat in the first six months of weight management. **METHODS:** One hundred overweight diabetic patients were enrolled in a structured weight management clinic and treated with orlistat plus behavioural interventions. Among other measures, weight, glucose control (HbA_{1c}) and drug treatments were recorded. Subjects were followed-up for a maximum of 24 months at intervals of 6 months, with a maximum treatment period of 24 months. **RESULTS:** The majority of subjects (90%) had type-2 diabetes. They had a median age of 55 years (IQR 47–63) and 55% were women. The mean BMI at baseline was 39.51 with a mean HbA_{1c} of 7.56%. The mean reduction in weight at 6 months was 7.1 kg ($p < 0.001$), with an average absolute HbA_{1c} improvement of 0.62% ($p < 0.001$). Of the 50 patients treated with insulin at baseline, three no longer required insulin by the 6 month follow up. Of those treated with insulin, the mean insulin dose was 130 iu (SD 135.4) at baseline and 90 iu (SD 125.4) at 6 months ($p < 0.001$). Twenty patients (45%) initially treated with oral hypoglycaemic agents alone reduced their dose after 6 months. Despite marked improvement in insulin sensitivity (baseline mean 1.24 iu/kg: 6 month mean 0.90 iu/kg ($p < 0.001$)) there was no correlation with BMI change. The average cost of diabetes treatment was £0.82 per day at baseline and £0.59 at 6 months (Δ 28%; $p < 0.001$). **CONCLUSIONS:** Orlistat therapy, in conjunction with a structured weight management programme, appears to reduce the need for concomitant diabetes medication irrespective of weight loss. This reduction is likely to translate into a large cost offset for orlistat treatment.

PDB7

THE METABOLIC EFFECTS OF ORLISTAT AND ROSIGLITAZONE ON INSULIN ACTION IN A GROUP OF CHINESE PATIENTS AFFECTED BY THE METABOLIC SYNDROME

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OBJECTIVES: To examine the effects of orlistat and rosiglitazone and assess the changes of cardiovascular risk factors in a group of Chinese patients affected by the metabolic syndrome. **METHODS:** In a prospective, 6-months randomized single-blinded placebo-controlled study, 58 Chinese participants with type-2 diabetes or impaired glucose tolerance, aged >18 years with a BMI of 23 kg/m2 or above were administered orally 120 mg orlistat three times daily, rosiglitazone 2 mg twice daily or placebo three times daily. Changes in clinical and metabolic parameters of the metabolic syndrome were monitored, including BMI, body fat, glycaemic control, lipid levels and drug tolerability. **RESULTS:** There were 20 individuals in the rosiglitazone group and 19 individuals in both the orlistat and placebo groups. There were statistically significant differences between the three groups in total cholesterol ($p = 0.001$), triglycerides ($p = 0.037$), LDL-cholesterol ($p = 0.001$), BMI ($p = 0.001$), hip ($p = 0.002$) and body fat ($p = 0.006$). The orlistat group demonstrated improved lipid profiles from baseline, especially on the reduction of total cholesterol (12% $p = 0.0005$) and LDL (21%, $p = 0.0002$). This was accompanied by improvements in the fasting insulin levels ($p = 0.07$) and Homeostatic Model Assessment (HOMA) scores ($p = 0.026$). In comparison, the rosiglitazone group exhibits maximum improvements in fasting insulin ($p = 0.004$), 2 hr-post OGTT insulin ($p = 0.004$) and HOMA scores ($p = 0.005$). Although statistically insignificant, there is a slight increase from baseline in the LDL levels (12%) and body fat (3.7%). **CONCLUSIONS:** To prevent progression to type-2 diabetes mellitus and its complications, early detection and implementation of appropriate treatment strategies for the metabolic syndrome is crucial. Both rosiglitazone and orlistat appear to be promising in treating the metabolic syndrome.

PDB8

CLINICAL BENEFITS OF PROLONGED-RELEASE NICOTINIC ACID (NIASPAN®) AND EZETIMIBE IN STATIN-TREATED TYPE-2 DIABETES PATIENTS FAILING TO REACH TARGET CHOLESTEROL LEVELS

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OBJECTIVES: To assess the clinical benefits of add-on treatment with Niaspan® (increases HDL-c) or ezetimibe (reduces LDL-c) on coronary heart disease (CHD) in Type-2 diabetes patients failing to reach target cholesterol levels on statin monotherapy. **METHODS:** Two models were developed to project the clinical benefits of treatment over 10 years. The first model (Monte Carlo simulation) was used to evaluate the impact of simvastatin treatment on lipid levels and identify patients with low HDL-c or high LDL-c. Baseline cohort characteristics were taken from the diabetic sub-population of the 4S study. Patients with LDL-c <3 mmol/L and HDL-c <1 mmol/L received add-on Niaspan®. Patients with LDL-c >3 mmol/L received add-on ezetimibe. Each add-on treatment was compared to statin monotherapy. Treatment effects for both drugs were taken from several clinical trials summarized in the European SPC. The second model (Markov model) was used to evaluate the cumulative incidence of CHD

events. Transition probabilities were based on Framingham risk formulae. **RESULTS:** Over 10 years, in Type-2 diabetes patients with controlled LDL-c and low HDL-c (<1 mmol/L), addition of Niaspan® (2 g daily) to statin treatment was projected to reduce the absolute incidence of MI (3.2%), angina (0.7%) and CHD death (1.6%) compared to statin monotherapy. Relative risk reductions were 13.3%, 12.5% and 13.1% respectively. In patients with elevated LDL-c (>3 mmol/L), ezetimibe plus statin was associated with a reduced absolute incidence for MI (2.3%), angina (0.5%) and CHD death (1.1%) versus statin alone. Relative risk reductions were 7.7%, 7.4% and 7.9% respectively. **CONCLUSIONS:** Over 10 years, both Niaspan® and ezetimibe may lead to substantial reductions in the cumulative incidence of CHD events in Type-2 diabetes patients failing to reach cholesterol targets with statin monotherapy. These findings highlight the potential long-term benefits of raising HDL-c in Type-2 diabetes patients with controlled LDL-c.

PDB9

PROJECTED IMPACT ON CORONARY HEART DISEASE AT 5, 10 AND 35 YEARS OF ADDING PROLONGED-RELEASE NICOTINIC ACID (NIASPAN®) TO STATIN TREATMENT IN PATIENTS WITH TYPE-2 DIABETES

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OBJECTIVES: To evaluate the clinical benefits of raising HDL-c by adding Niaspan® on coronary heart disease (CHD) endpoints in Type-2 diabetes patients on statin therapy. **METHODS:** Two successive models were developed to project long-term clinical benefits of treating patients over different time periods. The first model (Monte Carlo simulation) was used to evaluate the impact of simvastatin treatment on lipid levels and identify patients with low HDL-c. Baseline cohort characteristics and effects of statin treatment were taken from the diabetic subpopulation of the 4S study. In patients with HDL-c <1 mmol/L, treatment with statin plus add-on Niaspan® was compared to statin monotherapy. Niaspan® treatment effects were taken from several clinical trials as summarized in the European SPC. The second model was then used to simulate the development of CHD events based on the Framingham risk formulae. This Markov model included five states: no CHD, history of myocardial infarction (MI), history of MI and angina, and dead. Cycle length was one year. **RESULTS:** Addition of Niaspan® (2 g daily) to statin treatment was associated with a lower cumulative incidence of CHD events than statin monotherapy. Absolute risk reductions of 2.1%, 4.0%, and 8.1% for myocardial infarction, 0.5%, 0.9%, and 1.3% for angina, and 1.0%, 1.9%, and 4.0% for CHD death were projected at time horizons of 5, 10, and 35 years respectively. **CONCLUSIONS:** Due to its positive effect on HDL-c levels, addition of Niaspan® to statin treatment was projected to reduce the cumulative incidence of CHD events compared to statin monotherapy in type-2 diabetes patients with persistently low HDL-c. These data indicate that as the treatment period increases, the clinical benefits associated with statin plus Niaspan® may also increase compared to statin monotherapy.

PDB10

TYPE-2 DIABETES IN GERMANY: PREVALENCE AND MEDICATION USE

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OBJECTIVE: Type-2 diabetes is recognized as a growing problem across the world, with the number of individuals diagnosed with this disorder expected to approximately double in the next 25 years. The objective of this study is to examine the prevalence of Type-2 diabetes as well as trends in antidiabetic medication use in Germany. **METHODS:** Data for this study were obtained from the German Disease Analyzer—Mediplus database. All patients who were identified with Type-2 diabetes between 01/01/2001 and 12/31/2003 and who were at least 20 years of age when first identified as having Type-2 diabetes were included in the prevalence estimate (N = 45988). While the 2003 prevalence estimate was based on data from a three year window, patient characteristics and medication use was examined for each of the three calendar years. These cohorts consisted of patients identified with Type-2 diabetes who were at least age 20 during the year (N = 20766 for 2001; N = 22778 for 2002; and N = 23326 for 2003). **RESULTS:** The prevalence of Type-2 diabetes was estimated to be 3.93% in 2003. From 2001 to 2003, there was a decrease in the percentage of patients with Type-2 diabetes who were not receiving antidiabetic medication (from 34.28% to 28.27%; $p < 0.0001$) as well as a significant decrease in the use of sulfonylureas (from 20.02% to 16.02%; $p < 0.0001$). In contrast, there were significant increases in monotherapy insulin use (from 7.95% to 9.90%; $p < 0.0001$), monotherapy metformin use (from 14.04% to 18.71%; $p < 0.0001$), and oral combination antidiabetic medication use (from 14.34% to 16.99%; $p < 0.0001$) over the same time period. **CONCLUSIONS:** The prevalence estimate confirms that Type-2 diabetes is a significant health concern in Germany. Furthermore, recent trends demonstrate that physicians are increasingly likely to prescribe antidiabetic therapies for the treatment of this disease.

PDB11