

PDB4

#### LONG-TERM OUTCOMES OF SWITCHING PATIENTS WITH TYPE 2 DIABETES FROM BIPHASIC INSULIN TO BIPHASIC INSULIN ASPART 30/70: AN IMPROVE STUDY SUBGROUP ANALYSIS

Ligthelm R<sup>1</sup>, Christensen TE<sup>2</sup>, Thomsen TL<sup>2</sup>, Yang W<sup>3</sup><sup>1</sup>EHM, Hoofddorp, The Netherlands, <sup>2</sup>Novo Nordisk A/S, Virum, Denmark, <sup>3</sup>China-Japan Friendship Hospital, Beijing, Beijing, China

**OBJECTIVES:** The IMPROVE study includes results of 52,419 patient's after 26 weeks of treatment with biphasic insulin aspart 30/70 (BIAsp30) in routine care setting. The aim of this analysis was to project long-term clinical outcomes in patients with type 2 diabetes from the IMPROVE study switched from biphasic human insulin (BHI) to BIAsp30. **METHODS:** In total, 4,368 patients on BHI from the IMPROVE study were used in the present analysis. The CORE Diabetes Model was used to project long-term clinical outcomes based on the baseline characteristics (male 58.2%, mean age 57.0 years, duration of diabetes 10.7 years, HbA1c 9.2%, BMI 26.2 kg/m<sup>2</sup> and total daily insulin dose 32.8 IU). Patients were assumed to either continue on BHI, or switch to BIAsp30 and obtain the significant ( $p \leq 0.01$ ) treatment effects of BIAsp30 observed in the IMPROVE study (HbA1c improvement of 1.9 percentage points, 0.24 kg weight loss and 29.3 less major hypoglycemic events per 100 patient years). **RESULTS:** The improved glycemic control resulting from a switch from BHI to BIAsp30 led to a projected delay in the onset of any diabetes-related complications of 0.7 years (2.0 versus 1.3, respectively). E.g. the projected delay of suffering a myocardial infarction was 1.7 for BIAsp30 and 1.4 years BHI. The cumulative incidence of complications was projected to decrease with BIAsp30 in the majority of parameters studied, e.g. the cumulative incidence of severe vision loss was projected to decrease by 8.5% (1.3 %-point absolute risk reduction) and strokes by 8.6% (1.1 %-point absolute risk reduction). The average life expectancy was projected to increase by 1.5 years. **CONCLUSIONS:** The long-term health outcome projections based on endpoints reported in the IMPROVE study indicate that switching patients with type 2 diabetes from BHI to BIAsp30 will improve life expectancy, delay the onset of diabetes-related complications, and reduce their cumulative incidence over patient lifetimes.

PDB5

#### SYSTEMATIC REVIEW OF THE EFFICACY AND SAFETY OF VILDAGLIPTIN FOR TYPE 2 DIABETES MELLITUS

Walczak J, Nogas G, Organa M, Przada P, Potoczny R

Arcana Institute, Cracow, Poland

**OBJECTIVES:** The aim of the review was to compare the efficacy and safety of vildagliptin versus glimepiride as add-on therapy to metformin in patients with type 2 diabetes mellitus. **METHODS:** The analysis was performed in accordance with the rules of systematic review, based on the Cochrane Collaboration (Cochrane Reviewer's Handbook) guidelines and the Health Technology Assessment Agency in Poland recommendations. Literature search strategy was performed within the main medical databases: Medline, Cochrane Library, EMBASE, Biomed Central and CRD. **RESULTS:** one study of high quality was identified according to predefined selection criteria. The trial evaluated fifty-two-week effectiveness of vildagliptin plus metformin versus glimepiride plus metformin. The analysis disclosed non inferior efficacy of intervention and comparator in HbA1c reduction. The change in fasting plasma glucose was also comparable between groups. Patients in vildagliptin group more frequently reached a target HbA1c level of <7% without hypoglycaemia (50.9% of participants) than patients in glimepiride group (44.3% of participants). Furthermore vildagliptin was more efficient in body weight reduction; WMD = -1.79 (95% CI: -2.11; -1.47). The risk of hypoglycaemia episodes was higher within glimepiride therapy; RR = 0.10 (95% CI: 0.07; 0.16). Vildagliptin treatment resulted in lower incidence of adverse events, serious adverse events and discontinuation because of adverse events (respectively 74.5%, 7.1%, and 4.8% in vildagliptin group versus 81.1%, 9.5%, and 7.7% in glimepiride group). The risk of cardiovascular complications was higher in comparative group but it was not statistically significant. Dizziness, fatigue, asthenia, tremor, hyperhidrosis and hunger were significantly less frequent in vildagliptin group. **CONCLUSIONS:** Vildagliptin as add-on therapy to metformin is more efficient and safer technology than glimepiride combined with metformin in the treatment of type 2 diabetes mellitus.

PDB6

#### ADMINISTRATIVE CLAIMS ANALYSIS OF AN L-METHYLFOLATE COMBINATION PRODUCT IN PATIENTS WITH DIABETIC PERIPHERAL NEUROPATHY

Wade R<sup>1</sup>, Cai Q<sup>1</sup>, Thethi T<sup>2</sup><sup>1</sup>HealthCore, Inc, Wilmington, DE, USA, <sup>2</sup>Tulane University Health Sciences Center, New Orleans, LA, USA

Oral administration of the combination prescription product containing L-methylfolate, pyridoxal-5'-phosphate, and methylcobalamin (MPM) has shown to increase epidermal nerve fiber density in humans, reduce neuropathic pain and restore sensation in patients with diabetic neuropathy (DPN). It is believed to increase vascular perfusion through lowering homocysteine and increasing nitric oxide levels. **OBJECTIVES:** Evaluate the clinical and economic impact of orally-administered MPM on patients with diabetic peripheral neuropathy (DPN) in a managed care setting. **METHODS:** Data were obtained from the 30+ million member HealthCore Integrated Research Database. Patients with at least 1 claim for diabetes, antidiabetic agents and DPN and  $\geq 2$  claims for MPM between July 1, 2004 and April 30, 2007, with  $\geq 6$  months pre and  $\geq 12$  months post index eligibility were matched 2:1 on age, gender

and health plan region with non-MPM treated patients. Cost comparisons were performed on the population <65 years old to assure full capture of health care costs. **RESULTS:** A total of 89 MPM treated patients and 178 matched controls were identified, 65% were male and mean (SD) age was 60.1 ( $\pm 9.3$ ) years. MPM treated patients were more likely to be treated with anticonvulsants in the pre-index period ( $p < 0.01$ ). There was a 31% reduction in the use of anticonvulsants post-index for the MPM group and a 10% reduction in the control group. There was a meaningful albeit non-significant cost difference in the 12 month post-index DPN related costs between the <65 year old MPM and control groups (\$1029  $n = 56$  vs. \$1401  $n = 112$ ). **CONCLUSIONS:** This observational cohort study demonstrated a reduction in the use of anticonvulsant medication among the MPM cohort, perhaps denoting a reduction in the need for pain medication, and costs related to DPN were lower in the MPM group. Additional randomized controlled trials need to be conducted to validate these results.

PDB7

#### THE CLINICAL EFFECTIVENESS OF SOMATROPIN (GENOTROPIN®) IN CHILDREN WITH SHORT STATURE: A SYSTEMATIC REVIEW

Heatley RM<sup>1</sup>, Walsh C<sup>2</sup>, Loftus J<sup>3</sup><sup>1</sup>Evidence Research Unit, Macclesfield, UK, <sup>2</sup>Complete Medical Group, Macclesfield, UK,<sup>3</sup>Pfizer Ltd, Walton on the Hill, UK

**OBJECTIVES:** Genotropin® is a brand of somatropin (human growth hormone [GH]) licensed for the treatment of children with short stature due to: growth hormone deficiency (GHD), Prader-Willi syndrome (PWS), Turner syndrome (TS), chronic renal insufficiency (CRI) and those born small for gestational age (SGA). Although final height (FH) is probably the most effective outcome for measuring somatropin effectiveness, there is a lack of randomised controlled trial (RCT) data reporting FH and other important outcomes, such as quality of life (QoL) which is rarely reported for children. The objective of this systematic review (SR) of RCTs and observational studies was to investigate the efficacy and safety of Genotropin in children with these indications, and identify whether the lack of relevant RCT data in this therapy area can be supplemented with observational studies. **METHODS:** Predefined search terms were used to search eight electronic databases, including Medline and Embase, for published English language studies. Additionally, bibliographies of included articles were examined for relevant studies. RCTs or observational studies were retrieved if they included a population of children (<16 years) with GHD, PWS, TS, CRI or SGA treated with Genotropin. The main reported outcome measures included FH and short-term growth responses, e.g. growth velocity. **RESULTS:** Thirty RCTs and 37 observational studies were identified. No RCTs were identified that included data on QoL. One RCT and 11 observational studies reported data for FH. FH was consistently improved following treatment with Genotropin. Seven of the observational studies were based on data sourced from the Pfizer International Growth Survey (KIGS), which showed significant gains of up to 2.3 height standard deviation scores. **CONCLUSIONS:** This SR reveals the paucity of long-term RCTs reporting data on FH and QoL in children, thus highlighting the consequent importance of observational studies of GH therapy, such as KIGS, which reports FH.

PDB8

#### ANTIDIABETIC DRUG UTILIZATION IN A UNIVERSITY HEALTH CARE SETTING

Mousnad M<sup>1</sup>, Ibrahim MIM<sup>2</sup><sup>1</sup>Universiti Sains Malaysia, Penang, Malaysia, <sup>2</sup>Universiti Sains Malaysia, Penang, Malaysia

**OBJECTIVES:** Diabetes mellitus (DM) is a worldwide problem. Data regarding the utilization pattern of antidiabetics is lacking in Malaysia. The present study evaluated the prescribing trends of antidiabetic drugs in a university health care centre in Malaysia during the years 2002 and 2003. **METHODS:** Retrospective data for 2002 and 2003 was collected from the USM Center for Knowledge, Communication and Technology. A drug utilization study using the Anatomical Therapeutic Chemical classification and defined daily doses (ATC/DDD) methods was conducted. Selected drug use indicators as suggested by WHO/INRUD were used in this study. Prescribing prevalence was expressed by the DDD methodology. The utilization of antidiabetic drugs was expressed as the number of defined daily doses per 1000 inhabitants per day (DDD/1000/day). **RESULTS:** The number of antidiabetic patients was 300. Total 1289 and 1565 prescription data were collated from the database for the years 2002 and 2003, respectively. The total number of different drugs prescribed in 2002 and 2003 were 2982 and 3345, respectively. Among these, 1997 (67.0%) of drugs prescribed in 2002 and 2389 (71.4%) of drugs prescribed in 2003 were antidiabetics. In general, the consumption of antidiabetics in USM Health Centre increased from 3.4 DDD/1000/day in 2002 to 4.7 DDD/1000/day in 2003. Significant antidiabetic prescribing patterns related to metformin and gliclazide were observed in this study. Metformin was the most commonly prescribed drug while gliclazide was the most consumed drug. **CONCLUSIONS:** It is reasonable to conclude that diabetic medicine utilization is on increase. Much attention and effort should be directed towards establishing the burden of diabetes in USM in economic terms.

PDB9

#### IMPACT OF FDA SAFETY WARNINGS ON SUBSEQUENT DIABETES CARE FOR USERS OF ROSIGLITAZONE

Huse D, Bizier R

Thomson Reuters, Cambridge, MA, USA

**OBJECTIVES:** To understand the impact of the May 2007 safety warning about rosiglitazone from the US Food and Drug Administration (FDA) on the subsequent