regression analysis was used to control for demographic and clinical covariates. **RESULTS:** The final sample (unweighted N=7002; weighted N=14 million) had a mean age (±SE) = 61.2 (±0.2) years, mean BMI (±SE) = 32.2 (±0.1), and 50.4% were males. There was a significant difference in both the PCS-12 and MCS-12 scores of patients by BMI, controlling for covariates. Being obese (PCS = 40.1) or overweight (PCS = 36.5) were significantly worse compared to normal weight patients (PCS = 41.0, p < 0.001 for both), while being overweight was significantly associated with higher MCS-12 scores compared to being of normal weight (MCS = 50.9 vs 48.9, p = 0.038). **CONCLUSIONS:** Among diabetes patients, overweight patients had significantly higher mental health scores compared to their peers with normal weight, while being at least obese was significantly associated with lower physical health scores compared to non-obese patients.

**PDB110**

**CHALLENGE IN QUALITY OF LIFE (EQ-SD) AMONG TYPE 2 DIABETES MELLITUS PATIENTS INADEQUATELY CONTROLLED WITH METFORMIN PLUS SULFONYLUREA AND TREATED WITH DAPAFLIGLIZOIN AS TRIPLE THERAPY REGIMEN FOR 24 WEEKS**

Srinivasa C.1, Polweider W.1, Sugg J.1, Grandy S.1

1AstraZeneca, Mödling, Sweden, 2AstraZeneca R&D, Mödling, Sweden, 3AstraZeneca LP, Wilmington, DE, USA

**OBJECTIVES:** Dapagliflozin, a novel, selective, oral sodium–glucose co-transporter 2 (SGLT2) inhibitor, lowers glycated hemoglobin (HbA1c) along with reduction in body weight. This study evaluated health-related quality of life (HRQOL) among type 2 diabetes mellitus (T2DM) patients treated with dapagliflozin in triple therapy during a 24-week, randomized, double-blind, placebo-controlled study (NCT01392677) to evaluate the effect of dapagliflozin in combination with MET plus SU on HbA1c and body weight. Patients enrolled were ≥61 years old, had HbA1c ≥7.5% and with body mass index ≥25 kg/m² who had a significant glycemic control on combination of metformin (M) and sulfonylurea (SU) were enrolled in a 24-week, international, double-blind, randomized, placebo-controlled study (NCT01392677) to evaluate the effect of dapagliflozin in combination with MET plus SU on HbA1c and body weight. Patients completed the EuroQol Group EQ-SD survey at baseline and at weeks 12 and 24. The study was designed as a secondary analysis of data in patients treated with dapagliflozin 10 mg + MET + SU (n = 108) compared with patients treated with placebo + MET + SU (n = 108), based on ANCOVA model with treatment group as an effect and baseline value as a covariate. **RESULTS:** EQ-SD visual analog scale (VAS) responses were 72.4 (±3.1) and 65.7 (±2.8) in the T2D + SU + MET group and placebo group, respectively. The 24-week means were 78.8 (±1.7) and 75.9 (±1.9) (P = 0.02). VAS scores improved in both groups from baseline to week 24, however, there was no significant difference between groups (0.9, CI: -2.9, 4.8; p-value: 0.63) in adjustment from baseline. EQ-SD index (scores 0-1) baseline means were 0.84 (±0.16) and 0.85 (±0.16) for dapagliflozin and placebo, respectively. Corresponding 24-week values were 0.85 (±0.17) and 0.83 (±0.16); respectively. There was a trend for improved change from baseline (P = 0.005). Similar treatment responses were observed in people with diabetes in Bangladesh. **METHODS:** Patients with diabetes from five different countries who had experienced a non-severe hypoglycaemic event in the past 4 weeks were asked to take part in a nocturnal (N) and/or daytime (D) hypoglycaemia survey. The final sample (unweighted N = 111/1450). HRQOL was measured using the Impact of Weight – Lite (IWQOL-Lite) and Short Form 36 (SF-36) questionnaires. Similar to other dapagliflozin studies, patients in the present study maintained high HRQOL scores with dapagliflozin over a 24-week period.

**PDB111**

**THE ASSOCIATION OF HEALTH-RELATED QUALITY OF LIFE (HRQL) AND ACHIEVEMENT OF DISEASE MANAGEMENT GOALS IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM)**

Traina S.B.1, Pfarr E.2, Davisson F.1, Davenport E.2, Rampichini D.2, Pfarr E.2, Riemer C.1, Davenport E.1, Pfarr E.2

1RTI Health Solutions, Research Triangle Park, NC, USA, 2Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany

**OBJECTIVES:** Empagliflozin, an oral antidiabetic drug, inhibits the sodium-glucose cotransporter 2 and promotes urinary glucose excretion. Six of the phase 3 studies assessed efficacy and safety, including health outcomes, of empagliflozin as monotherapy or in combination with other oral antidiabetic treatments. The objective was to evaluate the impact of treatment on patient utility and health profiles measured (by the EQ-SD) and health care resource utilization (HCUR). **METHODS:** Descriptive analyses were performed for each individual trial and pooled across trials. Multivariable analyses were performed using linear mixed models for repeated measurements to account for the longitudinal data and significant baseline characteristics. **RESULTS:** The overall completion rate of the EQ-SD utility index and EQ-5D VAS at 24 weeks was above 80% in all treatment groups across trials. Patients’ utility and health profiles were high at baseline; most patients reported no problems with self-care [97% of empagliflozin; 96% of placebo], the most commonly reported problem was pain/discomfort [35% of empagliflozin, 36% of placebo reported at least moderate pain/discomfort]. After 24 weeks on treatment, patients reported few statistically significant differences between empagliflozin and placebo in patient utility (0.026, p=0.0268) and health profiles (3.4, p=0.0062) across trials. These differences were positive in three of the six trials in patient utility and adverse events between empagliflozin and placebo over 24 weeks were in general positive but small, which was not unexpected given that the majority of patients reported no problems at baseline. The percentage of patients with hospitalizations or outpatient visits was low with similar use reported among empagliflozin and placebo treatment groups.