baseline BMI at wk 56, respectively. A significant difference in change in BMI was seen for liraglutide 3.0 mg vs PBO: ETD -4.64%; 95% CI -7.14, -2.14; p=0.0003. A significant reduction in waist circumference with liraglutide 3.0 mg was shown at wk 56 (p=0.0126). Greater weight regain/rebound in BMI SDS at wk 82 was seen for liraglutide 3.0 mg vs PBO after drug discontinuation (ETD 0.15; 95% CI 0.07, 0.23; p=0.0002). There were no significant differences in blood pressure, fasting lipids, fasting plasma glucose or HbA1c at wk 56. No unexpected safety concerns and no severe hypoglycemia were reported. During treatment (0–56 wks), more adolescents in the liraglutide 3.0 mg (64.8%) vs PBO arm (36.5%) reported gastrointestinal adverse events (AEs), and 3 vs 5 adolescents, respectively, reported serious AEs. Mental health questionnaire results were similar in both arms at wk 56. No effect on growth or pubertal development was found.

Conclusions: This trial demonstrates clinically meaningful[4] weight loss in adolescents with obesity treated with liraglutide 3.0 mg as an adjunct to lifestyle therapy. The safety profile was similar to that observed in adults.

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Diabetes Mellitus and Glucose Metabolism

CLINICAL AND TRANSLATIONAL STUDIES IN DIABETES

Association of Baseline Cardio-Metabolic Parameters on the Treatment Effects of Empagliflozin When Added to Metformin in Patients with T2D

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MON-645

Sodium-glucose co-transporter-2 inhibitors (SGLT2i) are commonly used as 2nd-line therapy after metformin (MET) in patients with type 2 diabetes (T2D), and are now recommended in those with co-existing cardiovascular (CV) and/or chronic kidney disease (CKD). A better understanding of their clinical efficacy across the spectrum of cardio-metabolic characteristics may help to better individualize therapy. It was previously reported (Häring *et al., Diabetes Care* 2014) that empagliflozin (EMPA) 10 and 25 mg over 24 weeks vs placebo (PLB), when added to MET, led to clinically meaningful improvements in HbA1c, body weight (BW), and systolic blood pressure (SBP).

We explored the magnitude of these effects across categories of baseline (BL) HbA1c, BW, and SBP, comparing EMPA 10 mg (n=217) and 25 mg (n=213) vs PLB (n=207) in the following subgroups: HbA1c <8.5% and ≥8.5%; BW ≤70, 70-≤80, 80-≤90, and >90 kg; and SBP <120, 120-<140, and ≥140 mmHg. Analyses were performed for all randomized patients receiving ≥1 dose of study drug. Differences between treatment groups were assessed using ANCOVA and interaction tests (by respective BL factor and treatment-assignment). At week 24, EMPA 10 mg and 25 mg significantly (p<0.0001) reduced HbA1c vs PLB; the difference from PLB in adjusted mean [±SE] change was greater in the ≥8.5% vs <8.5% subgroup (EMPA 10 mg: -0.73 [±0.14]% vs -0.51 [±0.08]%, respectively; EMPA 25 mg: -0.97 [0.15]% vs -0.52 [0.08]%, respectively; interaction p: 0.029). EMPA also significantly (p<0.05) decreased BW vs PLB, with a trend for larger reductions in those with the highest BW at BL (EMPA 10/25 mg: -1.31 [±0.42]/-1.70 [±0.44], -1.23 [±0.53]/-0.74 [±0.54], -2.12 [±0.60]/-2.56 [±0.56] and -2.11 [±0.46]/-2.93 [±0.47] for ≤70, 70-≤80, 80-≤90, and >90 kg, respectively; interaction p: 0.075). Finally, EMPA significantly (p<0.05) lowered SBP vs PLB, but, in contrast, without significant differences across SBP categories (EMPA 10/25 mg: SBP <120 mg, -4.17 [±2.07]/-2.71 [±2.15]; SBP 120-<140, -4.35 [±1.48]/-4.98 [±1.49]; SBP ≥140, -4.28 [±2.38]/-6.29 [±2.33] mmHg; interaction p: 0.784). The number of patients reporting ≥1 adverse event (AE) was similar across treatment groups (PLB, 58.7%; EMPA 10 mg, 57.1%; EMPA 25 mg, 49.5%) and the AE profile was consistent with the drug's established safety profile. Confirmed hypoglycemic AEs were reported in 0.5%, 1.8%, and 1.4% of patients, respectively.

These data suggest that EMPA, when used as 2nd-line therapy after MET, is more effective in decreasing HbA1c and reducing BW in those with higher baseline values of these parameters but not for SBP. In addition to EMPA being a glucose-lowering agent recommended in patients with co-existing CVD and/or CKD, these data may help to tailor therapy as regards to important metabolic efficacy considerations.

Pediatric Endocrinology

UNDERSTANDING AND TREATING PEDIATRIC GROWTH DISORDERS

Mild Maternal Sleep Disordered Breathing in Pregnant Women Affects Growth Patterns of Head Circumference and Adiposity During the First Three Years of Life

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Background

The intrauterine environment affects growth and adiposity acquisition from the fetal period until adulthood. Mild sleep disordered breathing (SDB) during pregnancy is a common underdiagnosed medical condition in healthy women. We aimed to investigate the interaction between maternal isolated SDB during the third trimester of pregnancy and the offspring's growth and adiposity during the first three years of life.